



GUIDANCE ON

**Development and
Implementation of a
National Deployment and
Vaccination Plan for
Pandemic Influenza
Vaccines**



World Health
Organization

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Foreword

The information and recommendations contained in this guidance are the product of expert opinions, derived from international consultations and workshops which took place between 2008 and 2011. These reviews involved examination of available information, input from public health experts on existing national vaccination programmes, and on lessons learned from the deployment of vaccines in response to the outbreak of pandemic influenza A(H1N1) 2009. All external experts and contributors for all meetings and consultations have signed a declaration of interest statement in accordance with WHO policy. The declarations of interest are available on request.

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¹ Workshops on lessons learned from pandemic influenza A(H1N1) vaccine deployment and vaccination were held in Fiji, Lebanon, and the Philippines.

² Training workshops for developing and updating national deployment and vaccination plans (NDVPs) were held in Colombia, Denmark, Fiji, India, Morocco, Nigeria (2), Panama, Peru, the Philippines, Saint Kitts and Nevis, and Turkey.

Abbreviations and definitions

This guidance uses the following abbreviations and definitions:

AEFI	Adverse events following immunization
AESI	Adverse events of special interest
Ancillary items	Syringes, cold boxes, ice packs, and other items that are required for vaccination activities
CoL	Chief of Logistics
CoV	Chief of Vaccination
Chain of command	The order of authority among managers at different national, state, provincial, district, and local levels
Command and control	The collective methods for managing the deployment of vaccine and ancillary items
Deployment	The act of moving vaccine and ancillary items from the national point of receipt to the health providers who will administer it
EPI	Expanded Programme on Immunization (of national immunization programmes)
GLP	Good laboratory practices
IC	Incident commander
IMS	Inventory Management System. An active control programme that provides information about management of ordering, receiving, issuing, and shipment of vaccines and ancillary items
MIS	Management information system
NDVP	National deployment and vaccination plan
PIPP	Pandemic influenza preparedness plan
PDS	Post-deployment surveillance
SAE	Serious adverse event

SAGE	Strategic Advisory Group of Experts on immunization. The principal advisory group to the World Health Organization for vaccines and immunization.
SIA	Supplementary immunization activity
SOP	Standard operating procedure
Supply chain	The steps and network of manufacturers, transporters, and storage facilities that are involved in the movement of vaccine and ancillary items from the national level to the local levels that will administer them
Surge capacity	Additional resources and capabilities that exist for responding to the emergency distribution of vaccine and ancillary items during a pandemic
WHO	World Health Organization

Executive Summary

Vaccination plays a critical role in limiting the impact of an influenza pandemic and is an essential element of pandemic influenza preparedness and response. The World Health Organization (WHO) has prepared this guidance document and associated planning tools to assist countries to develop, assess, and update their National Deployment and Vaccination Plans (NDVPs). It is designed for public and private sector officials at all levels with responsibility for planning and managing deployment and vaccination operations.

Development of the guidance began in 2008. The initial draft was completed and field-tested shortly before the outbreak of influenza A(H1N1) 2009 and the declaration of a pandemic in June 2009. Consequently, it was used to guide countries in developing their pandemic NDVPs. It was revised in 2010–2011, incorporating experience and lessons learned from the pandemic at global, regional, and country levels and included key recommendations from global and regional workshops on NDVP implementation. The current document covers all the processes and structures that need to be functional for vaccine deployment and operations before and during a pandemic. A sample template for drafting an NDVP is included as an annex. In addition, a checklist to assist assessment of NDVPs has been developed and included in a supplementary document which is available through the WHO website at www.who.int/influenza_vaccines_plan/resources/deployment_guidance_supplementary/en/index.html.

Speed is of the essence to deliver a pandemic vaccine. The main goal is deployment within seven days of vaccine availability with subsequent rapid in-country vaccination. Before the pandemic vaccine is deployed, each country will need to decide on the selection of target populations for vaccination. The clinical and public health impact of the pandemic will determine the target groups and coverage goals for planning further deployment and defining vaccination strategies. Complying in advance with legal and regulatory requirements for importing and deploying a vaccine can be achieved by strengthening the capacity of national regulatory authorities, identifying regulatory pathways for licensing the use of a new vaccine in emergency conditions beforehand, and harmonizing licensing approaches.

Successful implementation of the NDVP will require high-level political commitment and investment in both human resources and facilities developments. Each country should build a vaccination strategy for pandemic vaccines based on their existing routine immunization capacity. It will need to mobilize a skilled workforce trained to manage the activities related to deployment and vaccination operations and establish a command and control system. Public health workers will need to be released for essential activities, such as clinical and immunization services, outbreak

investigations, monitoring, etc. Where possible, other activities and certain operations should be outsourced (i.e. delivery of vaccines, storage, waste management, etc.) Information management and telecommunications systems need to be enhanced to permit rapid exchange of information between offices at all levels.

Well-managed supply chain logistics and processes are central to successful deployment operations. This requires establishment of supply chain processes at each level, identification of the surge capacity for storage and transportation, and exercises to evaluate response preparedness. Where countries are unable to support all the additional capacity requirements, the use of private sector logistic resources may be considered. The vast amount of generated health-care waste must be safely collected, transported to designated sites, and properly disposed of, which will require increasing the capacity of the existing health-care waste systems of national routine immunization programmes. Where it is possible, use of the private sector may be considered.

Effective and evidence-based public risk communication may ensure acceptance and compliance to the vaccination policy. This requires an integrated approach, with a mix of social mobilization, interpersonal communication, and mass and local media and advocacy messages. Continuous and transparent communication on reported adverse events following immunization (AEFIs) is vital to maintain public trust. Countries need to increase their capacity for real-time evaluation of pandemic vaccine safety and effectiveness by strengthening their systems for post-deployment surveillance and management of AEFIs.

It is crucial that countries plan for deployment and vaccination well in advance of the next pandemic, and that they review their respective 2009 pandemic responses and operations for lessons learned. Those countries with NDVPs in place should review them using the guidance, while those that do not, should use this guidance to develop them. Countries should exercise and test their NDVPs, ensuring that they are regularly updated and integrated into their national pandemic influenza preparedness plan (PIPP).

Introduction

Background

Immunization against influenza is considered to be an essential public health intervention to control both seasonal epidemics and pandemic influenza. It is broadly accepted that vaccines can play a key role in limiting the impact of an influenza pandemic. Therefore, the deployment of and vaccination with pandemic influenza vaccine is a critical element of pandemic influenza preparedness and response.

Speed is of the essence to deliver a pandemic vaccine, and experience suggests a target of seven days from the time of its availability in-country.¹ In 2008, to support countries in this task, the World Health Organization (WHO) initiated a process to develop a guidance document to assist countries in the development of their national deployment and vaccination plans (NDVP) for pandemic vaccine. An NDVP covers all vaccine deployment and vaccination operations that need to be functional before and during a pandemic. It defines the processes and structures required for delivering pandemic vaccine and related supplies within seven days and rapidly vaccinating the targeted population. The NDVP can be a separate, stand-alone plan or an annex to the national pandemic influenza preparedness plan (PIPP). The guidance assumes that most countries will build on their national immunization programme to deploy and vaccinate using a pandemic vaccine.

WHO established the Pandemic Influenza Vaccine Deployment Initiative in response to the outbreak of influenza A(H1N1) 2009 and to deploy donated vaccines to countries seeking to protect their populations. One of the prerequisites for a country to receive donated vaccine was the development of an NDVP. WHO provided technical assistance to help countries develop their NDVPs using the initial version of this guidance. Between July and December 2009, ten workshops were conducted in the six WHO regions which trained representatives from 170 countries on how to prepare NDVPs.

The guidance was further developed into the final version in 2010–2011, incorporating experience and lessons learned from the response to pandemic (H1N1) 2009 at global, regional, and country levels. Countries that already have NDVPs may use the guidance to assess and update their NDVPs and those that do not may use the guidance to develop one.

¹ The seven-day time frame is evidence based, namely that the individual requirement for measurable protection (HI titres) after vaccination with seasonal influenza vaccine is approximately 14 days. This time frame protects individuals as quickly as possible, reduces disease transmission, and uses the efficacy of the vaccine to fight the disease. The successful eradication of smallpox operated on this principle, as do current efforts to eradicate poliomyelitis in many regions of the world.

PURPOSE

To provide guidance to the countries in developing, accessing, and updating their national deployment and vaccination plans on the use and deployment of a pandemic influenza vaccine.

Target audience

This guidance is written for authorities in the public and private sectors who are responsible for planning and managing deployment and vaccination operations at all levels.

Objectives

This guidance provides a framework and recommended actions for countries to:

- develop, assess, and update a detailed NDVP to deploy pandemic vaccines and other ancillary products within seven days to permit rapid vaccination of the target population;
- identify vaccination strategies and operational gaps and plan for surge capacity during a pandemic to deploy and vaccinate the target population quickly;
- establish a uniform management structure, command and control protocol as well as effective coordination, information management, and communication between all sectors of government, private, and civil society through which the vaccine will be deployed;
- develop micro-plans and standard operating procedures for the deployment and vaccination activities and prioritize actions on when to implement each and how to coordinate them;
- enhance or establish a post-deployment surveillance system;
- mobilize resources to support all activities related to deployment and vaccination; and
- exercise and test the NDVP over time to address changes in policies and technology.

Organization and scope of the guidance

This guidance consists of 10 chapters. Each chapter covers the major areas that support rapid deployment of vaccine and ancillary items as well as vaccination of target populations. It also contains templates, checklists, and spreadsheets in the supplementary documents. These documents focus on the following:

- management tasks in a series of essential steps;
- measurable indicators for managers to be able to monitor the progress and evaluate the effectiveness of deployment and vaccination activities; and
- identify problems, shortcomings, and other factors that may effect deployment operations as well as suggestions on how to resolve them.

The guidance does not address issues such as the determination of target groups and their numbers, the sequencing of priority groups for vaccination, the establishment of vaccination sites, procurement of vaccines, or fundraising. These issues will need to be defined by each country based on national policies and the epidemiology and severity of the pandemic influenza virus.

Developing and updating a national deployment and vaccination plan

Each chapter in the guidance document describes in detail the structure, processes, and activities that should be covered when preparing or updating NDVPs. A sample template has been developed to assist countries in developing and drafting their NDVP (Annex 1). The template is organized by each process or structure as presented in this guidance and was used by many countries to prepare their NDVP for pandemic influenza A(H1N1) 2009. Supplementary documents contain a checklist that includes questions managers should answer to assess their readiness to manage and execute deployment operations, an example of a plan of action, and a budget template. These additional documents are available through the WHO website at www.who.int/influenza_vaccines_plan/resources/deployment_guidance_supplementary/en/index.html

Responsible authorities and counterparts with existing NDVPs used to provide deployment and vaccination operations in response to the 2009 (H1N1) pandemic will need to update their plans. Countries should consider incorporating or integrating their NDVP into their national PIPP.

ESSENTIAL REQUIREMENTS FOR A DEPLOYMENT AND VACCINATION PLAN AT ALL LEVELS

The following essential requirements at all levels of the health system, in conjunction with existing procedures in place in countries, should be used to prepare for the deployment and utilization of vaccines:

- A national policy for using a pandemic influenza vaccine that is outlined in the PIPP.
- Plans for deploying the vaccine within seven days from the time it arrives in the country to the time health providers receive it.
- An accurate assessment of the operational gap and identification of resources needed to achieve the surge capacity required for deployment and vaccination.
- Sufficient numbers of trained and skilled personnel responsible for deploying the vaccine and vaccinating target populations.
- Building on existing public and private vaccine delivery systems.
- An information system and network for communicating to support deployment operations and a public communications plan.
- Assignment of funds to support deployment and vaccinations operations.

1. Defining vaccination strategies

1.1 Overview

Pandemic influenza A(H1N1) 2009 created uncertainties concerning its impact on patients' health and national infrastructure that were linked partly to whether or not the virus would evolve into a more aggressive form. Given the current global production infrastructure and capacity, our experience confirmed that no country can produce or purchase sufficient pandemic vaccines simultaneously for all of its population.¹ Therefore, when countries decide which target groups to immunize first, their decisions will define how best to implement deployment and vaccination activities.

Planning for the deployment and vaccination operations during a pandemic is the same, regardless of its severity, requiring vaccination of the majority of the population, or in moderate situations, where only selective groups with high risk for severe infection are targeted. The scope of the effort will be different but the goal is the same: to rapidly deploy and quickly vaccinate the targeted populations with specific pandemic influenza vaccines. The sequencing and strategies to vaccinate will determine the required logistics in supporting public information activities. Depending upon the course of action selected, the authorities in charge of vaccine deployment and vaccination operations will need to adjust the NDVP accordingly.

GOAL

Understand how the national decision on selection of target population and sequencing will affect the vaccination strategy and the support required for the national deployment and vaccination plan (NDVP).

1.2 Objectives

The purpose of this chapter is to:

- enable countries to understand the impact that the following will have on selecting a vaccine strategy and the planning process:
 - severity of the disease;

¹ As influenza vaccine production technology changes, the deployment and vaccination plans may require modification and testing to ensure that the optimum logistic support is planned for before the next pandemic.

-
- availability of a pandemic influenza vaccine;
 - sequencing of target groups; and
- use of the WHO Forecasting Tool for scenario analysis and micro planning.

1.3 Factors determining vaccination strategies

1.3.1 Severity of disease

Severity of disease depends upon the nature of the virus, which populations are affected and how, and the impact on essential infrastructure.

A severe scenario has the potential to disrupt the nation as a whole, and it is essential to maintain the functioning of civil society and protect the health infrastructure in order to save lives. This scenario will result in the selection of different vaccination strategies to provide vaccination to a wide range of the population and establish many vaccination sites at all levels. The availability of the pandemic influenza vaccine will determine the intensity of the operations to support such massive vaccination activities.

A moderate scenario will have less impact on society, but in order to protect lives, the government will need to prioritize at-risk groups who might suffer greater morbidity and mortality. This scenario will result in selective vaccination and fewer vaccination sites with shorter duration of operations.

1.3.2 Availability of pandemic vaccine

Today, vaccine availability is limited by the time required from developing vaccine candidate strains to the final product and manufacturing capacity. As the technology for producing vaccine is expected to change and the number of manufacturers is likely to increase over the next decade, more vaccine is likely to be available. However, in 2009, production of pandemic influenza vaccine was initially limited, resulting in governments having to prioritize which target groups to vaccinate.

1.4 Prioritizing and sequencing of target groups

The limited supplies of vaccine and its staggered delivery in 2009 compelled most countries to use a step-wise approach and sequence their population in priority order for pandemic influenza vaccination. In future pandemics, prioritization and sequencing of target groups will remain a national decision. Vaccinating certain groups of people before others to minimize the effect of a pandemic can be ethically justified on public health grounds, as can be protecting groups of people who are at increased risk due to the nature of their jobs.¹ Essential service providers, such as health-care workers, are considered a priority for vaccination, to enable continued functioning of the health-care structure.²

¹ *Ethical considerations in developing a public health response to pandemic influenza*. Geneva, World Health Organization, 2007, (WHO/CDS/EPR/GIP/2007.2).

² See Strategic Advisory Group of Experts on Immunization – report of the extraordinary meeting on the influenza A (H1N1) 2009 pandemic, 7 July 2009. Geneva, *Weekly Epidemiological Report*, Vol. 84, No. 30, 24 July 2009. (<http://www.who.int/wer/2009/wer8430.pdf>, accessed 25 June 2012.)

Once priority groups have been sequenced, each country can begin to plan the movement of personnel required at each level of the health system, as well as the receipt, storage, repackaging, and transportation of vaccine and ancillary supplies for vaccination.

1.5 Selecting vaccination strategies to use during a pandemic

The guidance assumes that governments will use their existing immunization service delivery structure to offer vaccination with pandemic vaccines. This was the case for most countries during the influenza A(H1N1) 2009 pandemic. A few countries established temporary networks of vaccination centres, with the advantage that routine health services were not affected by the population that was seeking pandemic vaccine.

1.5.1 Target populations and common strategies used during pandemic influenza A(H1N1) 2009

In line with the recommendations of the Strategic Advisory Group of Experts on Immunization (SAGE),¹ the targeting of priority groups in the vaccination campaigns during pandemic influenza A(H1N1) 2009 was consistent across regions and countries and generally included health-care workers, pregnant women, people with underlying conditions, and children. The strategies used for each target group during the pandemic are in Table 1.

Table 1

Target groups and vaccination strategies for a pandemic influenza outbreak

Target Groups	Vaccination Strategies
Health-care workers	Vaccination teams visited each health facility.
Pregnant women (regardless of their trimester)	Vaccination through specific campaigns or at fixed health centres or clinics.
Persons with underlying conditions (diabetes, chronic respiratory conditions, cardiac diseases, renal disorders, etc.)	Vaccines offered at disease-specific clinics or through fixed health facilities.
Age specific populations ^a <ul style="list-style-type: none"> • Children aged 6 months to 11 years • Adult and elderly populations 	<ul style="list-style-type: none"> • Vaccination using fixed health facilities and mobile teams visiting nurseries and schools. • Vaccination using temporary fixed sites, health facilities, and other public and private establishments.

^a Many countries in the Eastern Mediterranean Region also included participants of the Hajj and Umra seasons.

1.5.2 Universal vaccination

Countries that offered universal vaccination used a combination of public and private service providers. Those countries that used private service providers did not possess the required surge

¹ Ibid.

capacity at the beginning of the pandemic to vaccinate everybody. As demand waned for vaccine, there was less pressure for additional human resources. However, in a severe influenza pandemic with high morbidity and mortality, the demand for vaccine is likely to create severe stress on private service providers because of the lack of vaccinators and infrastructure. The ability to recruit additional vaccinators will require surge capacity building for human resources.

1.6 District level planning

Once the country has prioritized target groups and their sequencing, each district can begin planning their own deployment and vaccination operations. To assist planners in this effort, WHO has developed a forecasting tool as an aid for scenario analysis and micro-planning. Managers should review the different plans emanating from the district planners to ensure their inter-operability. While district plans should all contain similar sections, they should also take into account logistics and accessibility to targeted populations in their district through alternative routes. In many cases, individuals may seek their vaccination from a provider who is not normally their routine health-care provider.

Managers are encouraged to familiarize themselves with the WHO Forecasting Tool for scenario analysis and micro-planning in order to be able to simulate the impact of a mild and severe influenza pandemic on human resources, logistics, and budgets. The Forecasting Tool is included in the supplementary documents.

WHO FORECASTING TOOL

The WHO Forecasting Tool is an Excel-based spreadsheet, which provides information on equipment, supply, and budget requirements needed to support deployment and vaccination operations. It gives planners an idea on the population size to be vaccinated, number of vaccinators required (based on the number of people a single health-care worker is able to vaccinate within given timeframe), and impact of the presentation of the vaccine on logistics and cold chain, as well as on transportation requirements. The WHO Forecasting Tool is available at: http://www.who.int/immunization_delivery/systems_policy/logistics/en/index5.html

1.7 Budgeting

The choice of a particular vaccination strategy or combination of strategies determines the resources and support for completing the rapid vaccination of each target group. Review of different pandemic influenza A(H1N1) 2009 NDVPs indicates that the largest expenditures recorded were for fuel and per diem costs, regardless of the type of vaccine strategy selected. Countries are encouraged to review their expenditure data and use it to prepare estimated budgets for their target populations in advance of the next influenza pandemic. An example of a plan of action and budget template can be found in the supplementary documents.

1.8 Conclusion

It is a national decision to identify, select, and sequence target populations and define the vaccination strategies accordingly. Regardless of whether the pandemic requires vaccination of a majority of the population or only of selected groups, planning for operations will be the same and the goal will always be to deploy the vaccine within seven days and rapidly vaccinate the targeted population. Countries should ensure that their NDVPs can support both moderate and severe pandemic scenarios and, if gaps are found, they should strengthen their core processes and structures, including planning for the required surge capacity.

DEFINING VACCINATION STRATEGIES

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. Countries should use the experience of pandemic influenza A(H1N1) 2009 to review their operations and exercise both moderate and severe pandemic scenarios to ensure that their current health infrastructure and operational requirements are able to support these different vaccination scenarios.
2. Vaccine allocation and targeting guidance should be re-assessed periodically to take into account new scientific advances, changes in vaccine production capacity, and advances in other medical and public health response measures.
3. Identifying the risk groups and the number of people in each group is challenging. Therefore, careful planning will be required to determine what target groups should be vaccinated first and how to reach them, including modifying health information systems to provide the data for input into any pandemic response using a vaccine. Databases on the numbers of people with selected underlying conditions should be upgraded to facilitate identification and planning.
4. A defined vaccination strategy for offering vaccine to the public should be made clear through a public communication campaign to ensure acceptance. The decision-making process on the prioritization of target groups should be made more transparent to the public.
5. Partnerships and/or collaboration with other sectors including interministerial departments, business enterprises and private medical professionals are critical, and should be established or strengthened to support the required vaccination strategies and ensure high vaccine uptake.

2. Management and organization

2.1 Overview

It is essential that persons responsible for managing the national deployment and vaccination plan (NDVP) understand their responsibilities and coordination structure, including the structure in which they will function to ensure the deployment of vaccine in seven days and support to vaccination operations. The authorities and their management teams should include representatives from the ministry of health at the national, state/provincial, and district/local levels, as well as appropriate representatives from other government offices, non-governmental organizations, civil society, and the private sector.

This chapter discusses what authorities should plan before a pandemic and what they will have to manage during a pandemic to deploy and vaccinate with a pandemic influenza vaccine.

GOAL

Define and plan an effective managerial framework and system that ensures deployment of vaccine to designated distribution points within seven days and supports vaccination operations.

2.2 Objectives

Enable countries to:

- assess and develop effective processes and structures that need to be in place for managing deployment and vaccination operations;
- establish standard operating procedures and methods for sharing operational information that supports effective management and coordination at all levels;
- foster cooperation and coordination between agencies and organizations at all levels, in both the public and private sectors; and
- identify areas where surge capacity needs to be established during deployment and vaccination.

2.3 Establishing chain of command and management structure

Effective deployment of vaccine and vaccination will depend on the management of the planned activities and processes and ability of the managers to make rapid decisions at all levels. Structures and processes to support decision-making should include: an incident commander, a chief of logistics, and a chief of vaccination.

2.3.1 Incident Commander

This guidance refers to the person responsible for managing the country's overall pandemic response as the Incident Commander (IC). The IC is responsible for the overall development and implementation of a national pandemic influenza preparedness plan (PIPP). This includes command and control, supervisory structure, coordination of all stakeholders and human resources, communications and information technology for supporting operations, public information, budget and expenditure, legal issues, and security.

IC should delegate responsibilities for deploying vaccine and vaccinating to the Chief of Logistics (CoL) and the Chief of Vaccination activities (CoV). Countries may have different names for the IC, the CoL, and the CoV.

2.3.2 Chief of Logistics

The Chief of Logistics (CoL) is responsible for developing the deployment component of the NDVP for vaccine and related items. The CoL is in charge of the deployment committees, the logistic supervisory structure, communications and information technology for managing logistic operations, human resources, warehousing and stock inventory management, transportation, waste management, and budgeting and expenditure related to the deployment operations.

2.3.3 Chief of Vaccination

The Chief of Vaccination (CoV) is responsible for developing the vaccination component of the NDVP. The CoV oversees the vaccination field operations including supervisory structure, human resources and training, monitoring of vaccine safety, communication, and budgeting and expenditure related to the vaccination operations.

2.4 Command and control

2.4.1 Command and control structure

The command and control system established by the IC provides the protocols, oversight, accountability, and framework for rapid decision-making necessary to manage deployment and vaccination. To be effective, the IC should define a structure, decision-making processes, and command relationships to ensure delivery of the vaccine and ancillary supplies to each distribution point within seven days, and implementation of the vaccination plan.

Figure 1. Managing activities in support of vaccine deployment

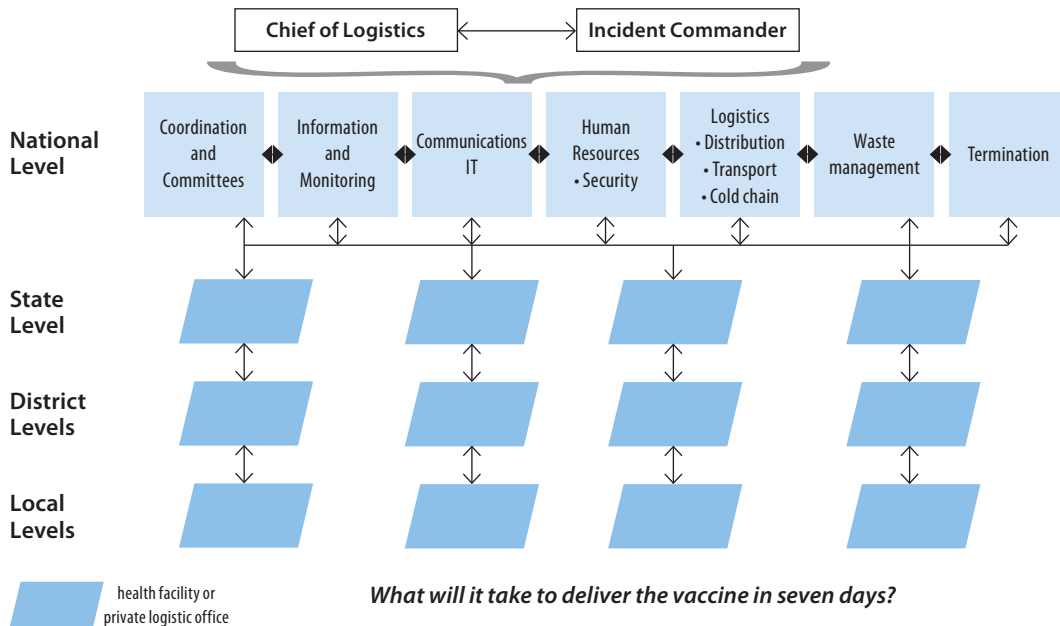


Figure 1 illustrates the complex environment of multiple functions operating at multiple levels – national, state/province, district, local – throughout a country that the CoL, CoV, and others must manage. Those who manage functions at each level will report to superiors in levels above them and manage subordinate managers below them. The chart implies that the IC, the CoL, and the CoV have a communication system that permits them to quickly communicate and pass data to each other up and down the system as well as laterally.

Experience from other disease control efforts has shown that the establishment of an effective command and control system depends on six essential elements. These are:

- **Processes:** Instruction and guidance that allow staff at all levels to perform required tasks, set up order of performance, and outline required information and criteria that has to be met for each task.
- **Decision-making:** Provides clear lines of decision-making authority where key offices/persons at each level in the deployment have specific responsibilities.
- **Communication:** Allows for the ability to communicate with all deployment participants in all parts of the country at all times.
- **Supervision:** Clear guidance for managers and supervisors that includes in-field training and oversight of staff efforts, together with rapid and effective correction of mistakes and resolution of problems.
- **Evaluation and monitoring:** Understanding how well deployment activities are progressing according to the deployment plan.

- Simulation exercises: Engaging in activities in the deployment plan before an event/outbreak to test staff performance and identify problems and weaknesses.

2.4.2 Command and control protocols

The basis for having a good command and control operations is to establish efficient processes as shown in the chart. These processes are known as command and control protocols. Table 2 illustrates the processes and activities of the command and control protocols that should be established by each office at state/provincial and district levels.

Table 2

Command and control protocols for a national response to pandemic influenza

Offices	Command and control protocol (state/provincial and district levels)
Incident Commander	<ul style="list-style-type: none"> • Responsible for managing a country's overall pandemic response, including development and implementation of a national PIPP. • Delegates responsibilities for deploying vaccine and vaccinating to the CoL and CoV. • In collaboration with the CoL and CoV, drafts the final report and outcomes on the deployment and vaccination activities.
Chief of Logistics	<ul style="list-style-type: none"> • The deployment component of the NDVP • A description of the roles and responsibilities of the key offices/persons • Contact information for members of deployment committees, other key authorities, and a duty roster • A proposed execution schedule covering shipments of vaccine and the mode of transport of each shipment • A security plan for personnel and vaccine • Process for vaccine reception, storage, transport, and distribution • Processes for data collection and information to display using a management information systems or an inventory management system • A standard format for information to be collected by each level • Process for monitoring and evaluating deployment activities
Chief of Vaccination	<ul style="list-style-type: none"> • The vaccination component of the NDVP^a • Contact information for members of deployment committees, other key authorities, and a duty roster • A security plan for personnel and vaccine • Processes for providing public information • Process establishing additional vaccination sites, if required • Processes for data collection and information to display using a management information system • Process for carrying out post-deployment surveillance and management of adverse events following immunization (AEFI) • Process for monitoring and evaluating vaccination activities

^a For more details, see Introduction: Developing and updating a national deployment and vaccination plan (NDVP) and Annex 1: Sample template for drafting an NDVP.

2.5 Coordination

Coordination plays a major role in effective management of deployment and vaccination. It is crucial that managers be involved in planning operations. Planning committees should be established and convened at each level. The objectives of the planning committees are:

- raise awareness of what must happen to deploy vaccine and vaccinate;
- ensure effective coordination of the resources and support of agencies, partners, and communities;
- establish decision-making processes for sending and receiving deployment information and making rapid adjustments to unforeseen events;
- inform the community from whom, when, and where the targeted population should seek their vaccine; and
- support managers in the execution of deployment and vaccination operations.

Committee members should come from a cross-section of multiple disciplines, including officials from all appropriate government agencies, civil society, and the private sector. Civil society representatives might include personnel from relevant associations, international organizations, the Red Cross/Red Crescent, other nongovernmental organizations, medical and nursing schools, and community, religious, and civic groups. The private sector may include vaccine manufacturers, communication, transportation, and waste management companies.

This multi-level, multi-agency, multi-disciplinary representation is important because in many countries, no single institution has the resources to deploy vaccine nationwide. Multisectoral representation also helps in obtaining additional resources.

2.6 Using the WHO Forecasting Tool for effective micro-planning

The WHO Forecasting Tool is designed to guide the process of planning cold chain capacity for managing vaccination campaigns, introducing new vaccines, and implementing other changes in national immunization programmes. The tool is described in detail in Section 1.6.

The tool assists supervisors, managers, logisticians, and others at all levels in establishing surge capacity and requirements for storage, distribution, implementation, and vaccination. It compares the current immunization schedule with different schedule scenarios and provides a detailed list of cold chain equipment and supplies needed at all levels, including the budget required for each scenario. It also provides a logistical analysis for various supplementary immunization activities (SIAs) and can estimate effectively the surge capacity required to complete a vaccination operation within different time frames.

2.7 Performance indicators

The IC, CoV, and CoL should establish performance indicators for the processes in place.

2.7.1 Potential indicators for evaluating management performance before the event:

- percent of states/provinces/districts that have personnel assigned to management positions and up-to-date lists of operations staff;
- percent of distribution points that have the capacity to communicate up and down the chain of command within 12 hours;
- percent of distribution points with a vaccine inventory management system that complies with national standards;
- percent of states/provinces/districts that have exercised their deployment and vaccination activities and have documented the surge capacity required; and
- percent of states/provinces/districts that have an up-to-date plan with cost estimates for a seven-day deployment.

2.7.2 Potential indicators for evaluating management performance during the event:

- number of scheduled shipments that left storage sites as planned;
- number of shipments that arrived in good condition;
- number of vaccine shipments that arrived with the corresponding ancillary supplies;
- number of supervisory reports received on time;
- number of doses administered versus doses distributed by health facility;
- average numbers of days between receipt of vaccine at each clinic or health facility and the date on which vaccination was offered to the target populations; and
- percentage of vaccine utilization and coverage by target groups.

2.8 Budgeting

The IC, CoL, and CoV, as well as managers at each level, need to carefully estimate the cost of vaccine deployment and vaccination operations to achieve a seven-day deployment schedule, including the possible deployment of a second dose. These costs should be incorporated into the country's pandemic preparedness plan and updated periodically. The supplementary documents include an example of a plan of action and a budget template for describing each activity; i.e. what must be done, how, by whom, and the estimated cost.

2.9 Conclusion

Establishment of an effective management framework, command and control, and coordination systems are each crucial for successful vaccine deployment within seven days and rapid vaccination of target populations. It is essential that those who are responsible for managing the NDVP fully understand their responsibilities, engage in effective coordination, and are clear about the chain of command and control systems.

MANAGEMENT AND ORGANIZATION

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. Countries should assess, update, and integrate their NDVP with their overall national pandemic influenza preparedness plan (PIPP).
2. Agreement should be reached with all partners and stakeholders in the health sector, as well as the non-health sector, on an overall framework for vaccine deployment and on the roles and responsibilities of all those involved.
3. A cross-functional, cross-regional communication channel should be established that involves all stakeholders in order to facilitate information sharing.
4. Managing deployment and vaccination operations efficiently will require that managers review critical components for making rapid decisions and plan for surge capacity. These components include communication networks, management information systems/inventory management systems (MIS/IMS), storage, logistics and supply chain management, logistic support for moving staff and supervisors, a supervisory plan, and planning all resource requirements to support operations.
5. Political commitment from the highest national level should be secured, and a national task force should be established to support smooth implementation. Planning committees should be established at all levels.
6. Establishing partnerships and/or collaborating with other sectors of society, interministerial departments, and involving business enterprises and private medical professionals will be critical to supporting the vaccination campaigns.

3. Legal and regulatory planning

3.1 Overview

Although legal and regulatory concerns are not technically under the responsibility of the Chief of Logistics (CoL), this guidance includes them because the national and international laws and regulations that affect pandemic influenza vaccine must be followed during an emergency. Such laws and regulations apply to the movement and use of vaccine from the time it leaves the manufacturer, or the World Health Organization's (WHO) stockpile, to the time it is administered. Failure to comply with legal requirements in advance of an event may seriously delay the delivery of vaccine when pandemic operations commence. With good preparation, a country can avoid the stress and delays of having to comply with legal requirements during an event.

Every country has its own laws and regulations for importing and using vaccine so this chapter does not discuss specific legal statutes. Instead, it outlines steps to help the CoL ensure that the appropriate authorities comply with the legal and regulatory procedures and complete the related processes before vaccine is needed.

GOAL

Ensure the appropriate agency or ministry completes the necessary legal and regulatory steps to import and use a pandemic vaccine and related medical items before an event.

3.2 Objectives

Enable the CoL to:

- understand the importance of existing legal and regulatory requirements, both international and national, before an event; and
- ensure that the appropriate authorities comply with all legal and regulatory requirements and complete the related procedures for importing, warehousing, packaging, shipping, and using vaccine before it is needed.

3.3 Main legal tasks of the Chief of Logistics

As the person responsible for managing vaccine deployment, the CoL¹ must:

- Understand the legal and regulatory requirements for importing and using vaccine;
- Contact the offices that are responsible for complying with the requirements and determine the additional information they require; and
- Ensure that the responsible offices take the necessary steps in advance to ensure that the deployment of vaccine is not impeded by unforeseen legal constraints.

3.4 Analysis of existing laws and regulations

In order for health providers to receive vaccine and ancillary items without delay and within seven days, the CoL should seek the assistance of legal counsel to identify:

- legal requirements for importing, warehousing, packaging, shipping, and using a pandemic influenza vaccine and other medical items as well as the regulations governing the medical waste disposal generated;
- legal authorizations and documents required for the importation and stockpiling of vaccine and medical items as well as documents and contracts to be processed prior to their arrival;
- specific legal obligations concerning vaccine and medical items that customs, regulatory authorities, airport authorities, transportation and logistics companies, and other stakeholders must follow; and
- vaccine manufacturers' documentation required by national regulatory authorities and other agencies, such as production protocols, lot-release documents, dossiers of clinical trials, vaccine registration requirements, and liability issues for using vaccines and the existing laws on compensation to patients who suffer adverse events after vaccination.

To ensure the submission of all documents and the timely completion of approval processes, the CoL needs to:

- determine what activities need to be accomplished and by which office;
- establish the timetable for obtaining the required authorizations and for preparing the paperwork; and
- contact offices and/or private organizations responsible for legal regulatory issues to determine what is needed, what information other offices or legal bodies have to provide, and who receives the information.

Meeting legal requirements may be a matter of completing necessary forms before a pandemic. However, the effort to identify and resolve legal and regulatory issues related to deployment may uncover areas that need attention. For example: documents may not be clear or processes may not

¹ For simplicity, this guidance calls on the CoL to oversee and manage the legal issues regarding importation and use of a pandemic influenza vaccine. Each country will have its own officer and office to assume the tasks discussed in this chapter.

exist for emergency approval to use a pandemic vaccine; clearance of vaccine through customs; or waivers of customs duties and logistic certifications during emergencies. In each case, the CoL will need to request legal assistance from the appropriate offices to intervene with the relevant authorities to resolve problems that could impede the rapid delivery of vaccine during an event.

3.5 Adaptation of existing laws

Some countries may need to modify existing laws to allow the deployment of vaccine during a public health emergency.¹ For instance, a new pandemic vaccine may not be fully licensed by a country when it is needed. A country may have to change its laws or regulations to allow an official to issue a conditional license for import and use. Such changes may require considerable time particularly to educate lawmakers on the need for change and to provide them with the appropriate technical and/or medical terminology to modify the law. Changes in laws, regulations, and processes that affect the importation and deployment of a vaccine must be circulated to all persons and offices involved.

3.6 Evaluation

Evaluations of the deployment plan and exercises to test deployment preparedness should include legal issues. The legal offices that are involved in the above activities should be involved in planning and conducting the exercises.

3.7 Budgeting

Pandemic influenza A(H1N1) 2009 showed that the national regulatory authorities in many countries did not have the required resources to manage the various legal and regulatory matters for importing and licensing pandemic influenza vaccines. A provision of the budget should be made for this component when developing or updating an NDVP.

3.8 Conclusion

The national and international laws and regulations that affect pandemic influenza vaccine must be followed during an emergency. Satisfying the legal and regulatory requirements for importing and deploying a vaccine is time consuming and failure to comply with regulations in advance may seriously delay delivery of vaccines. With thorough preparation prior to a pandemic, countries can avoid the pressure and delays of having to comply with legal requirements during a public health emergency.

¹ A public health emergency of international concern (PHEIC) is declared by the Director-General of the World Health Organization upon notification from States Parties that a disease outbreak with potential for transmission across national borders is occurring. For more information on public health emergencies and PHEICs, see: International Health Regulations (2005) Second Edition. Geneva, World Health Organization, 2008.

LEGAL AND REGULATORY PLANNING

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. The regulatory pathway for a vaccine to be used during a pandemic should be identified beforehand since the routine regulatory pathway cannot be applied for new vaccines used under public health emergency conditions. Developing regulatory pathways specific to seasonal and pandemic influenza would facilitate deployment.
2. Harmonized regulatory licensing approaches for vaccines during a pandemic should be investigated, including the establishment of vaccine registration via fast-track and/or public health emergency registration pathways. The set of standard and acceptable product regulatory documentation necessary for each donated vaccine and ancillary product shipment during a pandemic should be identified and agreed upon in advance.
3. The impact on the overall regulatory process of granting provisional vaccine licenses in manufacturing countries which are later converted to full licensure should be considered.
4. Strengthening the national regulatory and legal requirements is crucial to enable fast track and/or emergency registration for immediate use of the vaccine. The capacity of the national regulatory authorities should be strengthened for efficient review of regulatory documentation provided by manufacturers, or for governments to respond to public health emergencies. Their roles and responsibilities should be clearly specified in the NDVP and the pandemic influenza preparedness plan (PIPP).
5. The legal offices in appropriate agencies (i.e. ministry of health, customs/interior, airport administration, logistic services, and other stakeholders) should be consulted well in advance to establish contacts and exchange information. A list of key individuals and their contact information should be created, entered in the CoL's management information system, and updated regularly.
6. Changes in national laws, regulations, and processes that affect the importation and deployment of a vaccine must be communicated to all persons and offices involved. Forms, documents, and other legal documentation should be prepared well in advance and updated as required.

4. Communication and information

4.1 Overview

During influenza pandemics, effective communication and information allows managers to understand events and adjust response activities to ensure their successful implementation. Rapid and effective decision-making depends on information and data accessibility and sharing among managers and staff at all levels as well as among various stakeholders. This is part of a management information system (MIS). Such real-time information enables managers to track location of vaccine, pinpoint problems, and contact those who can solve them. This requires not only information and data that supports effective decision-making and its communication but also an infrastructure in place to support it.

Most information and data required by the CoL and CoV to plan and monitor deployment and vaccination operations are the same, therefore they will need to work together to integrate their information and data needs into one MIS.

This chapter discusses the information and data that supports effective decision-making and its communication. It also discusses the infrastructure needed to support communication.

GOALS

Ensure that the management information system that supports deployment and vaccination operations provide the CoL, CoV, managers, and staff with the information they need to make effective decisions and manage operations.

Evaluate whether communications hardware must be upgraded or backed up, and arrange for redundant capabilities in case the primary information system fails.

4.2 Objectives

Enable the CoL and the CoV to:

- understand the information and data that are needed for deployment and vaccination operations and the standard formats and infrastructure that must exist to communicate it;
- document the country's communications and information management systems at all levels, and determine how well they can support vaccine deployment within seven days; and

-
- work with the office responsible for the MIS that will support deployment to ensure it has sufficient storage for the required information.

4.3 Information for human resources management

The CoL and CoV should review the existing human resource information systems and confirm that they can adequately support deployment and vaccination operations. Ideally the systems should hold and display information in a standard format, as determined by the CoL, to facilitate management of deployment personnel by managers at all levels.

The information should be easily accessible either in secure computerized or paper-based systems and provide:

- personnel data, including professional profiles and skills;
- job descriptions or tasks assigned to each staff member;
- training and estimated operational costs for training, including developing and reproducing training materials; and
- health status of staff members, including their vaccination records.

Managers should test and update the system periodically to identify gaps for improvement before a pandemic. Such testing may highlight the need to update or replace inadequate systems. Updating data in the system will ensure personnel data accurately reflect their availability for operations or additional skills that can better support deployment and vaccination planning.

4.4 Managing information for vaccine inventories,¹ movement, and waste disposal

Many countries have systems to manage their medical and pharmaceutical inventories. These inventory management systems (IMS) track the arrival, quantity, storage, issuance, dispatch, and shipment of vaccines and medical supplies. In countries where the private sector provides health services, private contractors may have similar systems. Some of these systems are paper-based and others are computerized. The CoL needs to confirm that the speed and timeliness of the information provided can adequately support vaccine deployment within seven days.

The uniformity of information in the systems and the way they present and report information should be evaluated in the areas described below.

4.4.1 Stock inventory management

Information on the receipt and shipment of vaccine is essential to ensure vaccine reaches health-care providers in seven days. Real-time reports on stock level are critical. Timely and accurate provision of this information depends on the capability and compatibility of the system that each

¹ Chapter 7 provides detailed information that supports the movement of the vaccine from its receipt at a national level to its delivery to health-care providers who administer it. Section 7.4.1 provides an overview of the basic information and data that should be part of any management information system used during deployment.

state, province, district, and/or private sector company uses for stock inventory management. All systems should hold information in a standard format to support transferring data between multiple systems at various levels. They should also present information in a standardized format, as determined by the CoL, to prevent misinterpretation.

To evaluate existing stock inventory systems, the CoL/CoV should:

- ensure that each distribution point uses a compatible system to capture and integrate data between all levels and process it in a standardized format;
- if paper-based systems are used, standardize the types of information recorded at each level;
- decide whether to upgrade or acquire new software, if current inventory management software cannot provide information fast enough to support deployment;
- assess whether existing inventory management systems can display and produce reports on:
 - vaccines quantity: by supplier, vial size, adjuvant if provided separately, lot number and expiration date;
 - cold boxes, vaccine carriers, and ice packs: quantity, volume, and weight of loaded cold boxes;
 - syringes: number of syringes per box and number, volume, and weight of boxes to be shipped to each distribution point, including lot numbers and expiration dates; and
 - safety boxes: number, volume, and weight shipped to each health facility.
- assess completeness of information on health facilities at each level, including their storage facilities, personnel contact details, and geographic terrain/environment;
- review systems' adequacy of reporting and screen displays to assess their completeness and clarity; and
- assess reporting mechanism from one level to another and ensure an alternative reporting mechanism to avoid any delay in reporting problems due to interruption of routine reporting mechanisms.

4.4.2 Information on the movement of vaccine

Each country should define information it needs to track movement of vaccine from the national level to individual health-care providers. This should include location and mechanical condition of transport vehicles, condition of routes (ground, water, and/or air), weather, and en-route security issues. The systems should use standard formats for holding, displaying, and sending information. Most importantly, they must provide managers the information they need to quickly respond to problems.

To facilitate decision-making, the CoL should display a transportation grid of the country's roads, airways, and waterways that shows the distance and time to travel between distribution points and health facilities as well as the location of fuel and repair depots. This information will help managers schedule shipments, assign drivers and transport, anticipate shipment arrivals, and respond to

problems related to fuel and mechanical breakdowns. Global positioning systems (GPS) for vehicle fleets enhance management's ability to coordinate movement and quickly identify problems.

The CoL should consult professional staff or companies for assistance in providing or upgrading a system that tracks vaccine movement. Ideally, the system should be computerized and web-based.

4.4.3 Information for managing waste collection and disposal¹

To determine whether sufficient surge capacity exists to properly collect, store, and dispose of medical waste generated by immunization, the CoL should collect and evaluate the following information:

- national codes and regulations for collection and disposal of medical waste, especially injection-associated waste;
- details on all existing facilities that can be used for the disposal of medical waste and the estimated capacity of waste disposal that each can process daily;
- estimates on the total amount of waste that each immunization site will generate on a daily basis (based on the local population to be vaccinated);
- routes to collect and transport waste to disposal facilities and the responsible party assigned to collect it;
- list of the regions that do not have access to a waste-disposal facility;
- details of private contractors who are qualified and authorized to collect and dispose of medical waste; and
- estimates on the cost of collecting and disposing of waste at each level including outsourcing.

4.5 Maintaining and protecting information

Protection of information in the MISs is critical and requires that countries have clear procedures for updating, accessing, and backing up information to prevent data loss or compromise. Technical personnel will have to be on duty at all times throughout the deployment period to fix problems as they occur and to provide user support. MISs may have to function for weeks in case pandemic response requires a second dose of vaccine.

4.6 Evaluating the current communications network

The Incident Commander (IC) should work with government agencies and private communications firms to identify gaps and establish the most current communication methods and systems and plan for the required surge capacity ahead of a pandemic. Areas where communication services are limited or non-existent should be mapped out and incorporated into the MIS. Areas lacking access

¹ Chapter 8 discusses Waste Management and provides guidance for the Chief of Logistics and other responsible officials to manage and plan surge capacity for the safe disposal of used injection equipment, vaccine vials, and other hazardous medical waste.

to a communication grid may benefit from special efforts using more sophisticated technologies such as satellite phones.

To establish contingency plans in case of failure of primary systems, e.g. cell phones and land-line phones, the CoL should meet with the ministries responsible for national communications systems as well as agencies that can provide additional capacities. Amateur radio operators may offer an alternative, though not necessarily for the entire country. Police and military may provide communications in remote areas. In extreme situations, the military may be the only organization that can provide a working communications system, and their agreement to support communication during an event should be secured in advance.

The CoL should plan to exercise established communication procedures and periodically test existing networks, servers, and backup procedures to ensure that primary and secondary communications systems will function properly during an influenza pandemic.

The checklist in the supplementary documents will assist in gathering country-specific information and communications systems and evaluating their readiness to support deployment.

4.7 Budgeting

Most governments will review pandemic-related improvements to their communication and information systems within the broader context of the MIS in supporting other emergency response. Resources that are needed to upgrade the MIS will probably be needed as part of the national pandemic influenza preparedness plan (PIPP).

Countries are encouraged to review operational expenditures incurred during their pandemic influenza A(H1N1) 2009 response. Using exercises for evaluating communication systems in association with the information from the 2009 pandemic operations will enable managers at each level to prepare an operational budget to support information and communication activities in deployment and vaccination operations.

4.8 Conclusion

Rapid and effective decision-making depends on the ability to access, receive, and forward information and data rapidly between managers and staff at all levels, thereby enabling them to track vaccine and localize problems. This requires the collection of information and data as well as an infrastructure that needs to be in place to support it. Actions required to improve communication and information systems need to be carried out in advance of the next influenza pandemic.

COMMUNICATION AND INFORMATION

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. Countries should review and strengthen the information management and communications systems that support deployment and vaccination operations to ensure they can provide managers and staff with the information necessary to make effective decisions and manage vaccine deployment and vaccination operations.
2. A back-up reporting system for vaccine operations should be established in case of a disruption in the routine reporting system. The communications hardware should be evaluated to determine whether it requires upgrading and ensure it has redundant capabilities in case the primary information system fails.

5. Human resources and security

5.1 Overview

Deployment of pandemic influenza vaccine in seven days and rapid vaccination of the target population will require numerous additional personnel with the correct skill-set who are trained, motivated and supported.

During a pandemic, staff may be unavailable due to sickness or injury, and some staff may be already retired. Therefore, the Incident Commander (IC) needs to create a contingency plan that anticipates personnel shortages and minimizes their impact. An essential part of the emergency or contingency plan includes efforts to ensure that staff members remain healthy and able to perform to the best of their ability and that their families are supported. Human resources requirements should be identified and personnel training should be completed ahead of an influenza pandemic.

In addition, efforts should be made to ensure that managers and staff are protected and secure to do their jobs. With the confirmation of pandemic influenza A(H1N1) in June 2009, the World Health Organization (WHO) recommended that health-care workers be the first group to receive a dose of the pandemic influenza vaccine. To complement efforts being carried out by countries to mitigate the impact of the influenza pandemic, WHO conducted a series of workshops in all regions to train ministry of health staff on developing a deployment and vaccination plan.

GOALS

Ensure sufficient availability of skilled and trained personnel to support pandemic vaccine deployment and vaccination operations.

Ensure safety and security of personnel, infrastructure, facilities, equipment, inventories, and operations.

5.2 Objectives

Enable the Chief of Logistics (CoL) and the Chief of Vaccination (CoV) to:

- plan for acquiring and maintaining an adequate, skilled, and trained workforce and understand the actions that are important for managing personnel; and
- develop a security plan for protecting staff, equipment, facilities, vaccine, and ancillary items.

5.3 Skills and training

Effective deployment of the vaccine and use of different vaccination strategies will depend on how well the experience and skills of staff members fit the requirements of their respective jobs. The CoL and CoV need to establish operational tasks at each level to determine the skill categories required, identify the profile and quantity of health personnel available in the private sector, and outline the responsibilities of staff members and teams.

Attributes and skills that personnel possess and training they receive will be major determinants in the quality of their performance during deployment and vaccination operations. Staff and managers must be trained to work on their own and as part of a team and be capable of coordinating with other teams throughout the chain of command. Training activities to build surge capacity should be conducted in the following areas: supervision; technical and administrative support; information technology and communications; supply chain management; and security and safety.

5.3.1 Assessing staff needs

In general, the above-mentioned functional categories, including the number of personnel in each category, will depend on the number of shipments, quantity of vaccine needed at assigned distribution points, as well as the number and location of vaccination sites, routes, distances, types of transport, as well as the number of target groups to be vaccinated.

To plan for surge capacity in human resources, the CoL and CoV should:

- update or prepare terms of reference for each category of personnel, determine how many individuals are required, list their contact information, and ensure that staff members understand their responsibilities;
- prepare a staff roster, taking into account that some locations will require staffing at all times, and assess personal circumstances of staff members before assigning them to specific jobs;
- conduct exercises to assess additional staff required to perform assigned duties and identify additional training needs for individual staff or teams; and
- repeat the above steps, if the pandemic influenza preparedness plan (PIPP) has not been updated or when important changes in vaccination policies or technologies are made.

Countries that offered the pandemic influenza A(H1N1) 2009 vaccine should review their staffing records to estimate human resource requirements for a possible severe influenza pandemic. This will allow for appropriate updating of NDVPs. When additional human resources are required, managers should seek assistance from other ministries, non-governmental organizations, civil society, and the private sector.

5.3.2 Roles and responsibilities of personnel

To ensure sufficient human resources with the appropriate skill sets, managers should prepare job descriptions for every function. Each description should define the tasks and responsibilities a staff member may be given as well as the skills required to perform their job. Step-by-step instructions

on how staff should perform specific tasks and improve performance also should be developed. This will help team members and their supervisors assess the skills individual staff members will need to improve their performance.

In addition, managers should discuss what is expected of each staff member, assess whether staff members are capable of performing assigned tasks, and identify changes that will improve staff performance. Likewise, lessons learned from exercises will provide means for staff and managers to improve their performance.

5.4 Capacity building

5.4.1 Staff and manager training

Training for both staff and managers should include:

- basic and specific skills to ensure efficient performance;
- training team members to ensure team work; and
- team coordination training to ensure teams coordinate effectively with other teams throughout the chain of command.

Multiple methods exist for training staff. Each of these has an associated cost and different requirements. Two frequently used approaches include either general deployment-related training sponsored by other exercises or pandemic-specific training. An opportunity should be taken to train and assess staff during responses to other emergencies. While these may be different from an influenza pandemic, response activities undertaken during exercises are useful for helping managers identify areas requiring additional training and to test certain components of the national deployment and vaccination plan (NDVP).

Regular exercise of assigned tasks is a third and particularly effective method to train staff and to evaluate their performance. Although full-scale exercises are expensive and time consuming, smaller scale exercises can test various areas of the NDVP and focus on achieving effective performance in those specific areas.

Training could include functional areas such as information technology and communications, transportation, administration of a vaccine in mass campaigns, warehousing, maintenance of vaccines and other products within the cold chain, safe injections, and post-deployment surveillance, as well as supervision, administrative and technical support, and security and safety.

To plan training sessions, a manager should:

- develop a simple but comprehensive curriculum and training materials using simple visual aids providing bibliographic references for those who wish to have more information;
- use role playing to encourage participation and dialogue to impart a sense of ease; and
- keep training sessions short.

Periodically, teams should get refresher training to maintain their proficiency and to enable them to understand changes in existing or new policies and technology.

5.4.2 Manager training

Training for managers should focus on:

- working within the chain of command for detecting problems and resolving them quickly or identifying processes that lack good management oversight;
- guiding staff to meet objectives and deadlines, involving them in needs assessment (i.e. identifying when, by whom, and what tasks have to be performed), and providing in-field training;
- establishing performance indicators to assess staff performance;
- ensuring staff security and welfare; and
- managing information and data in the management information system (MIS) and making best decisions with given information in existence and time available.

5.5 Security

Managers must ensure the security of their personnel, equipment, work facilities, and vaccine and supplies designated for distribution. Pandemics cause anxiety and fear in affected populations, which may necessitate establishment of a secure environment for receiving, storing, and managing vaccine supplies.

To establish a secure working environment, the CoL and CoV should:

- work with the appropriate government offices and agencies to plan for potential security problems before an event and establish contractual agreements with other regions and private companies to assist in the event of unforeseen emergencies during the deployment;
- visit and understand the situation in regions with a history of security problems, including those with long travel distances, and meet with community leaders in high-risk areas and invite them to join a security committee;
- implement a procedure to issue badges to personnel to control access to deployment facilities and identify legitimate deployment staff;
- where possible, provide supervisors and their staff with communication devices such as two-way radios so they can request assistance in high-risk areas in case of need; train staff on avoiding and dealing with risky situations; monitor reports of security breaches and public disorder to anticipate where potential problems may occur; and
- meet with government agencies that track weather conditions to receive regular updates on transport conditions (roads, air, and waterways); consult with the military on improving security; and participate in security meetings and exercises.

5.6 Welfare of human resources

Security plans established by managers should also protect the well-being of staff and their families. Staff will be more likely to stay on the job if they know their family members are taken care of. The security plan should, therefore, anticipate the need to monitor the health and well-being of both staff and family members and provide prophylactic antivirals and vaccine as well as medical care to both when illness occurs.

In addition, managers should:

- coordinate provision of basic needs such as food, beverages, hygiene facilities and rest areas;
- provide personal protective clothing to staff handling vaccines in cold rooms;
- make available a means for staff to contact their families during operations at all times;
- ensure procedures and funds are in place for staff working overtime; and
- create and maintain an up-to-date recall roster for personnel and companies contracted to provide security support and ensure availability of mental health professionals to support personnel.

5.7 Budgeting

The NDVP should include funds for activities that support recruitment and preparation of training materials and training exercises that should be carried out prior to a pandemic as well as activities to support all staff, protect assets, and implement security plans for deployment and vaccination activities. Review of some countries' NDVPs from pandemic influenza A(H1N1) 2009 show that funds were required to prepare job descriptions, provide training, produce health education materials for health-care workers about the characteristics and circulation of the pandemic influenza virus, and conduct meetings.

5.8 Conclusion

Effective deployment of vaccine and the use of various vaccination strategies depends on how well staff members' skills and experience fit the requirements of the work. Efforts should be made to ensure that managers and staff are secure to do their job. This action involves not only protecting human resources, but also ensuring managers and staff perform with excellence and they and their families remain healthy.

HUMAN RESOURCES AND SECURITY

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. Assessment of the existing human resources and matching them with the required jobs should be done in advance. Hiring additional personnel should follow if funds permit.
2. Surge capacity planning for human resources will be required to improve implementation and execution of activities for vaccine deployment and vaccination operations. Involvement of other staff and relevant ministries, as well as other personnel and retired staff, will leverage more resources for surge capacity.
3. Outsourcing certain deployment and vaccination operations release staff to be available for other activities and helps to avoid disruption of other essential medical services.
4. A micro-plan for staff training is essential to provide the skilled personnel for supporting operations and human resources capacity building. Health-care workers should be trained to work with vaccinating target groups not in the routine immunization programmes.
5. Management training of supervisors is critical and shortage of supervisors should be addressed by strengthening interdepartmental collaboration within the ministries of health.
6. Providing for the welfare and security of health-care workers and other personnel responding to a pandemic is important to ensure their ability to perform the required work.

6. Public communication

6.1 Overview

In recent years, there has been substantial and increasing public discussion and debate about influenza vaccine efficacy and safety. Questions about the speed with which the pandemic influenza A(H1N1) 2009 vaccine was produced and rumours concerning safety issues circulated rapidly. This in turn resulted in misinformation and fed fears regarding exposure to products that were perceived as being unsafe for individuals and their families.

Looking back on the lessons from the 2009 pandemic response, these perceptions, combined with the effect of rapid information outlets and dissemination (i.e. 24-hour news coverage, social media, etc.) meant that information or misinformation on vaccines moved quickly and often unchecked through communities and social networks. These information outlets and networks are now considered important channels of communication and, as demonstrated by the 2009 pandemic, public health officials were, at times, and often still are unable to monitor and respond swiftly.

A lack of communication specialists in different domains, including media monitoring, social media, and social marketing, means that many countries are not prepared to mitigate and deal with rumours and misinformation. A number of countries reported that more support for communication and better public-information strategies could improve the overall uptake of pandemic vaccines.

Factors and reasons for influenza vaccine hesitancy vary significantly among different target populations. Some may be concerned about the safety of a vaccine that they consider new and untested, while others are unable to perceive their risk of infection or some may subscribe to rumours about ulterior motives behind vaccination campaigns.

Similarly, different target groups may not be reached in similar ways. A mainstream/mass media campaign, for example, is an effective way to educate the population about pandemic influenza and its dangers, but not necessarily the right channel to provide technical information on vaccination, or for conveying specific information to risk groups such as pregnant women, health-care workers, and those with underlying chronic disease.

Communicating with the public and specific target populations before, during, and after vaccine deployment and vaccination campaigns requires an integrated approach. This includes a mix of social mobilization, interpersonal communication, mass and local media, social media, and advocacy messages and channels. Effective evidence-based communication, therefore, should include those directly involved in vaccination operations including media, priority groups, and the general population.

GOAL

Understand steps and key communication principles for developing an evidence-based public communication strategy that generates demand for vaccine and raises acceptance regarding key issues.

6.2 Objectives

Enable those responsible for pandemic communications to:

- understand the need to integrate available evidence into multiple forms of communication to focus on changing or maintaining public behaviour in support of vaccination;
- understand basic principles of communicating with the general public during an outbreak and identify challenges that may exist in convincing target groups to seek vaccination; and
- be able to develop an evidence-based communications strategy, structure, and plan for various stages of vaccine deployment, i.e. before, during, and after.

6.3 Integrated communications approach

An integrated communications approach includes:

- gathering credible scientific/medical evidence to support points of communication;
- risk communication through media;
- social mobilization; and
- individual behavioural change.

In order to successfully achieve targets for vaccination, enable the public to make informed decisions, and effectively manage the media, pandemic influenza vaccine communications need to take into account an array of environmental, social, and behavioural determinants. Communications should use an integrated approach, focusing on using different modalities to convince the public to seek vaccination, and monitoring and measuring effectiveness through social mobilization and individual behaviour change.

6.4 Developing a communications strategy

A communications strategy should be developed and should describe actions a country will take to achieve a high rate of immunization among its target groups and the methods it will use to explain to other groups why they may not receive vaccine in the initial campaign. The strategy should be part of a country's pandemic influenza preparedness plan (PIPP).

The goal of the strategy is to ensure the uptake of vaccine by targeted groups and general acceptance of the vaccination campaign by the wider population. There are other important aspects of the campaign, but its central focus should be influencing human behaviour as supported by

evidence so that people act to protect themselves from being infected and infecting others. In this respect, all evidence-based communication activities should strive to maximize the benefits of and minimize the barriers to vaccination.

A critical part of the strategy, and one that is frequently disregarded, is monitoring communications before and during a vaccination event as well as documenting and recording vaccination operations and communication approaches employed. These actions enable future vaccination campaign managers to evaluate, learn from, and build on past experiences.

6.5 Communication challenges

Key barriers that will impede acceptance of vaccine by the public should be identified by the team responsible for developing the communications strategy. These challenges may include the following:

- explaining a new virus and its risks to a wide audience including the assessment of uncertainties;
- explaining the vaccine and assuring the public that it is safe;
- communicating when and where vaccine will be available as well as prioritization of groups to be vaccinated;
- managing surplus and shortages in vaccine demand and any resulting adverse effects; and
- build advocacy among health-care workers to address skepticism about the disease and vaccine as well as concerns from other target groups, particularly pregnant women.

6.6 Outbreak communication principles

In planning and implementing its pandemic communications strategy, a country should ensure the strategy embodies such key principles as proper evidence gathered, trust, timely announcements, transparency and planning. For a comprehensive description of these principles, see *WHO Outbreak Communications Guidelines*.¹

6.7 A proposed communication strategy

The proposed communications strategy covers three stages of vaccine deployment and vaccination operations: before, during, and after. It includes how to cooperate with other partners and work with the mainstream media to reach the widest number of people with the most general messages. It discusses how to seek the support of civic, religious, and public opinion leaders to help spread evidence-based information about the importance of vaccinating target groups. To reach health-care providers and their personnel, countries are encouraged to work with professional medical associations and to interact directly with health-care workers to build advocacy on the need to be vaccinated and how they can help to encourage the public to do the same.

¹ *WHO Outbreak Communications Guidelines*. Geneva, World Health Organization, 2005.
(<http://www.who.int/infectious-disease-news/IDdocs/whocds200528/whocds200528en.pdf>, accessed 25 June 2012.)

Countries need to create a strategy that meets their particular social, economic, and cultural situation. Simply adopting the strategy of another country or the messages it uses may fail, although reviewing other countries' communication strategies can be helpful. The strategy should reflect the priorities of the government and the needs of its population. The messages a country uses to reach the population needs to be tested for relevance and effectiveness with the targeted audiences. The strategy should include monitoring messages which should be modified to reflect changes in the population's behaviour.

Countries should consider the following strategy and messages as guidance rather than a template for their communications plan.

6.7.1 Communication strategy outline and timeline

Most communication strategies will include an introduction, scope and objectives, timeframe, target groups, main activities, key messages, monitoring and evaluating, and budget. Each section should have subsections that describe activities, management roles and responsibilities, a schedule, and a budget for all three stages of vaccine deployment and vaccination.

6.7.1.1 Before the arrival of the vaccine:

■ Planning

Objectives:

- Prepare the public with appropriate information before the vaccine arrives, ensure that the concerns raised by the public have been addressed, and use the opportunity to remind the public how it can protect itself from the disease in question.
- Find effective means of communicating that all WHO-recommended vaccines have been tested and are safe, that the benefits of vaccination far outweigh the risks, and that the great majority of adverse events, if caused by a vaccine, are mild or transient in nature, whereas the disease which the vaccine prevents can be life-threatening.
- Ensure that communications has a central role in the planning and decision-making process.

The months and weeks before the planned arrival of vaccines are critical to a successful vaccination campaign. Evidence should be used to reinforce information about pandemic influenza and what individuals can do to protect themselves and others from infection as well as identify and address public concerns.

Key activities:

1. Developing messages and strategies

The country should develop and define pandemic vaccine policy that clearly explains specific priority groups and what the reasons are. This policy should be made widely available. A survey to assess the needs of public and priority groups towards vaccination can be conducted and

communications materials should be developed or adapted accordingly. The communications team should pre-test developed messages to ensure their acceptability by targeted groups and meet with individuals or focus groups from targeted populations and guide them through discussions to understand their point of view and concerns.

2. Managing processes and structures to support the communications plan

A list of appropriate communications staff should be developed with designation of responsibilities, such as those who develop and approve communications materials including spokespersons. A central location should be identified for communications operations. Standard operating procedures (SOPs), delineating who communicates what and when, who generates and approves communications products, and who coordinates with other stakeholders are keys to success. A series of workshops, training sessions, and meetings with media officers, key staff including health-care workers, and stakeholders on communications issues should be organized. Educational materials for local health-care facilities should be provided. A campaign targeting health-care workers should be launched to inform them about the pandemic and vaccine, their need to be vaccinated, and the importance of and need for their help in encouraging other priority groups to accept vaccination.

Meetings with all partners, such as government departments at all levels, professional associations, religious associations and religious leaders, and international and non-governmental organizations, should be organized. Communication methods and modes of information sharing such as newspaper, radio, and television should also be identified. Where Internet connectivity exists, public health officials should coordinate their web postings with WHO so both have identical materials on their websites. Advocates, or champions, from within the targeted groups to support vaccination communications could be designated.

Public health officials and government leaders should respond to interview requests, meetings and speaking engagements on pandemic influenza and the vaccine. Information as to why vaccine is not available to all should be provided to the public prior to the vaccination campaign and at the vaccination sites.

A monitoring mechanism should be created to monitor communications activities and their impact on public perceptions and behaviour. An evaluation team should be established and an evaluation tool developed for use after the vaccination campaign has been completed.

6.7.1.2 During vaccine deployment and vaccination campaign:

■ Implementation of the plan

Objectives:

- Keep the public informed about how the campaign is progressing, the sequencing of each target group, and when and where to get vaccinated.
- Help segments of the population that are not targeted for receiving vaccination understand why and what they can do to protect themselves against the virus.

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- Monitor public messages to detect acceptance of the vaccine and any negative reactions; adjust communication material accordingly,

Key activities:

At the beginning of the campaign, the public health authority should hold a press conference to announce the start and explain the basics of the plan to the public. Through targeted messaging – official correspondence, literature, meetings, public outreach, and so on – communication teams should ensure that health-care staff and other priority groups know where and when the vaccines are available.

The chief of vaccination (CoV) should continue discussions with health-care workers and priority groups to determine whether they have any concerns and whether the messages are clear. Public reaction and vaccination-associated adverse events should be monitored and shared with the relevant bodies within the country and with appropriate personnel from WHO. The public should be informed on suspected adverse events and what is being done to investigate and manage them.¹

Experiences regarding vaccine deployment should be documented using a standard template. Up-to-date documentation on the deployment process complements monitoring and evaluation findings and enables a Member State or region to present narrative reports, both during and after deployment.

6.7.1.3 After vaccination campaign:

■ Monitoring, evaluating and documenting

Objectives:

- Record lessons learned from the initial campaign in order to improve future efforts. Document actions or processes in the communication plans that need correcting and that may be required to support delivery of a second dose.
- Evaluate and analyze public communication activities and alter communications strategies for future vaccination events.

Key activities:

Results of vaccination campaign, including the number of people vaccinated, adverse events, and overall impact, should be announced officially. Lessons learned, including public attitudes from all sectors, should be reviewed, documented, and shared. Procedures and expenditures should be modified where necessary to prepare for the delivery of remaining vaccine and second dose and for a future pandemic.

¹ Chapter 9 covers post-deployment surveillance and management of adverse effects following immunization.

6.8 Budgeting

Countries are encouraged to review operational expenditures incurred during their pandemic influenza A(H1N1) 2009 period. Using information from 2009 operations should enable managers to prepare an operational budget to support public communication efforts for deployment and vaccination operations during the next pandemic.

6.9 Conclusion

Information and communication campaigns play a crucial role in informing stakeholders on the impact of pandemic influenza and the benefits of vaccination, but they may not necessarily ensure acceptance of priority groups on vaccination. An effective communication plan could generate public acceptance for vaccination based on available evidence and awareness. This requires an integrated communications approach including a mix of risk communication strategy, adjustment of communication messages through monitoring and feedback, involving those directly responsible for vaccination operations, priority groups, and the general population.

PUBLIC COMMUNICATION

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. Countries should document success and failure related to social mobilization and communication for pandemic influenza vaccine and draw lessons learned from the pandemic influenza A(H1N1) 2009 experience. The communication component/plan should be reviewed and updated accordingly.
2. National authorities could invest more effort in communicating best available evidence, uncertainties, risks, and benefits of vaccination, and monitoring all response procedures.
3. Accurate information will need to be provided to the public in a timely manner to ensure that it understands and supports a pandemic influenza campaign. A lesson learned from most countries is that more communication on vaccine safety is needed at the time of vaccination operations.
4. Involving civic society and community-based groups, engaging their leaders, and responding to obstacles are the core of social mobilization. Many countries report that local government involvement proved to be one of the most important elements in mobilizing the community during the 2009 pandemic.
5. Media and the public behaviour/reaction regarding vaccination should be monitored and actions taken accordingly.¹ This includes modifying the key messages, using statistics to illustrate the objectives of the vaccine, ensuring transparency in managing vaccination campaigns, engaging popular personalities, and intensifying activities to target the main opponents of the vaccine.
6. Internal communication with health-care workers should start early. Any negative attitudes of health-care workers towards vaccination should be investigated. Targeting general practitioners, nurses, emergency room staff, and other health-system points of contact for outreach and convincing them of the need for vaccination will make them allies in the vaccination campaign.

¹ Strategies to manage the impact of the media include monitoring and addressing public reactions to media information and ensuring ongoing and appropriate messages, with changes as needed. Special focus should be given to vaccine-related adverse events, misleading information, and information related to changes in activities.

7. Supply chain management

7.1 Overview

This chapter provides information on the steps for receiving pandemic influenza vaccine and related items at the national level, transporting them to and processing them at intermediate levels, and finally delivering them to health providers who will immunize the public. The functions that manage and control the movement of vaccine and related items through the logistical process are called supply chain management. Effective management of these processes is essential for deploying vaccine within seven days.

Supply chain management processes include receiving, storing (warehousing), packing, and transporting vaccines and ancillary supplies to designated points within a country. The processes also include management of critical information on inventories (including accurate, real-time tracking of vaccine supplies), storage (including items delivered to and from warehouses), handling of materials, packaging, repackaging (bundling and/or packaging products such as needles and syringes together), distribution schedules, and transportation resources (for ground, air and/or waterways).

GOAL

Ensure that the supply chain processes have the capacity to receive, store, package and safely ship the pandemic influenza vaccine and ancillary items to specified distribution points within seven days.

7.2 Objectives

Enable the chief of logistics (CoL) to:

- understand supply chain management processes required to successfully deploy vaccine and ancillary items within seven days;
- document the capacity of the country's supply chain logistic system, identify its gaps, and prepare surge capacity along with the budget to support it; and
- collect information to manage vaccine deployment and update the country's pandemic preparedness plan.

7.3 Core functions

The CoL's primary responsibility is to plan and manage supply chain operations, including financial and administrative tasks that support the operations.

7.3.1 *Pre-event planning*

To adequately plan the supply chain network for an entire country, the CoL must have staff with logistics experience and knowledge. The CoL should collect information and lessons learned from those who were responsible for managing the supply chain of pandemic influenza A(H1N1) 2009 vaccine, and use this information to update the country's supply chain processes in support of its national deployment and vaccination plan (NDVP).

Countries that have conducted vaccination campaigns in recent years will have personnel who are invaluable in planning supply chain operations. In countries that do not carry out such campaigns, the CoL should seek advice from private sector companies that distribute their own products and have staff who manage distribution.

The CoL should designate one or more national warehouses to receive shipments of vaccine and ancillary items from manufacturers. National warehouses will ship to distribution and other points throughout the country, including regional, district, and sub-district warehouses. In countries where influenza vaccines are produced, a variant of these types of distribution networks should exist and such countries should instruct producers to ship vaccines directly to their regional, district, or sub-district warehouses.

7.3.1.1 **Developing and updating the deployment component of the NDVP**

To create or update the current deployment component of the NDVP, activities that are critical in the supply chain management process should be covered, including human resources, communication, and security management. In the plan, the CoL must describe all objectives and activities related to supply chain logistic processes, map current logistic capacity for delivering a vaccine within seven days, and determine the gap between existing resources and possible needs during an influenza pandemic. Capacities of national and other warehouses to receive and store large quantities of vaccine and to rapidly repackage it into smaller quantities for dispatch to assigned distribution points should be assessed.

Additionally, the CoL needs to work with counterparts at appropriate state/provincial and district levels to prepare a supply chain management chart that identifies movement of vaccines and ancillary items in real time from the national level, down through state/provincial and district levels, to local end users. Coordination with colleagues responsible for information technologies and communication will be required to develop specifications for the information needed to support supply-chain logistic processes. Contracts with all suppliers and transportation firms that support deployment should be established or updated.

Once finished, the deployment component should include calculations for:

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- the quantities/volumes of vaccine that must be shipped to each of the distribution points;
 - the capacity required to temporarily store vaccine at each level;
 - the quantities of cold boxes required;
 - the capacity to produce coolant packs at the sites that ship vaccine;
 - the estimated amount of medical waste generated during the event; and
 - estimations of surge capacity planning.

The plan should also cover transportation resources (air, land and water) required and include supporting procedures, processes, forms, checklists and reports to support deployment. It should include estimated budget associated with supply operations and planned dates for exercises to test preparedness.

The supplementary documents contain a checklist with recommended standards and/or criteria to use in assessing whether a country's current deployment plan includes relevant supply chain logistic processes and structures required to deploy vaccine within seven days.

7.3.2 Deployment operations

Vaccine delivery will not be a one-time event but a continuous effort for the duration of the pandemic because most countries will receive required quantities of vaccine in multiple shipments from the manufacturer over a period of time, and local health authorities will provide the sequence by which their populations are vaccinated as vaccine arrives. This was the case with pandemic influenza A(H1N1) 2009.¹

Activities described below must be planned for by the CoL while planning or reviewing deployment operations.

7.3.2.1 Activating the supply chain network

Operation: Notify all warehouses and transport operations to recall personnel and be ready to receive, package, and ship vaccine.

Before an event

- Record and maintain contact information for all managers and staff, and lists of all facilities and those who must be contacted to provide services.
- Conduct periodic exercises to test communication channels to ensure availability of key personnel and essential contacts.
- Plan the layout for receiving, storing, and packing operations in each warehouse or distribution point.

¹ *Main operational lessons learnt from the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative, Report of a meeting held in Geneva, Switzerland, 13–15 December 2010.* Geneva, World Health Organization, 2010.
(http://www.who.int/influenza_vaccines_plan/resources/deployment/en/index.html, accessed 25 June 2012.)

During an event

- Summon deployment personnel to report for duty and badge all personnel to control warehouse access.
- Notify government facilities that deployment operations are beginning and activate commercial storage facilities.
- Start delivery of supplies (ice packs, cold boxes, shipping cartons) and services (food, water, hygiene) to support warehouse operations, and ensure warehouse and transportation equipment are in place, fueled, and ready to operate and all vehicle operators have maps of points where they will be delivering.
- Activate communication, information, and inventory management systems for supporting deployment operations; test and issue communication devices.

7.3.2.2 Tracking vaccine and related items

Operation: Track the shipments of vaccine and related items received at each distribution point.

Before an event

- Map the warehouses where the vaccine will arrive, including private warehouses, and record each point in the management information system (MIS).
- Obtain necessary documents to clear the vaccine through customs before its arrival and release to the health authorities responsible.¹

During an event

- If a process for authorizing importation of pandemic vaccine does not exist, request a temporary authorization from the office in charge of vaccine importation.
- Count the quantity of vaccine that arrives and inspect temperature monitoring devices in vaccine shipments; record this information and note any discrepancies in the count, integrity, and temperature of received items.
- Sign for all shipments; maintain a meticulous record of the number of doses, lot numbers, and expiry dates in the inventory management system (IMS).
- Maintain signed records identifying who received, repackaged, and shipped vaccine to ensure accountability, and issue prompt reports of receipt of vaccines at destination points.

7.3.2.3 Storing vaccine and ancillary items at correct temperatures

Operation: Store vaccine and ancillary items temporarily at national, state/province, and district warehouses prior to shipment to designated points.

¹ See Chapter 3 on Legal and Regulatory Planning Issues.

Before an event

- Identify government facilities at national, state/province, and district levels that can store vaccine and other temperature-sensitive items.
- Contract private-sector warehouses that store refrigerated products for additional storage capacity, if government facilities are insufficient, and maintain signed copies of contractual agreements for use in activating these facilities when an event occurs.
- Confirm staff are informed on the correct storage temperatures for the pandemic influenza vaccine and its adjuvant, if the latter is part of the product.
- Ensure that each storage facility has adequate staffing to handle large quantities of vaccine, maintains its equipment in good working condition, and has security systems to prevent theft.
- Evaluate existing facilities, particularly those that store large volume of vaccines, to ensure that each maintains its equipment in good working condition and can maintain the vaccine at specified temperatures while in storage. Back-up generators with a minimum three-day fuel supply and procedures developed to monitor and record temperatures and to detect problems before the vaccine is invalidated¹ should be in place.
- Periodically evaluate commercial facilities, including their cold-chain practices without notification, or when there is a change in ownership or management.

During an event

- Provide the delivery status of incoming shipments to storage facilities and reports from the IMS to management to verify what has been received.
- Store the vaccine in designated areas/shelves in cold rooms or refrigerators, monitor the temperature of refrigeration equipment, and ensure that only authorized staff have access to warehouses with access controlled by security staff.
- Ensure adequate supplies of ice packs, cold boxes, and shipping containers.

7.3.2.4 Repackaging vaccines and ancillary items

Operation: Large shipments of vaccine and ancillary items will arrive at designated national warehouses or distribution points. The warehouses will then divide shipments into smaller batches, repackage them, and ship them to designated points. The process will be repeated until all health providers in the country receive their vaccine.²

¹ The cold life of a shipping container filled with coolant packs is based on the time (hours and minutes) the container can keep vaccine at +2 °C to +8 °C when ambient temperature is +32 °C. For more information on maintaining the vaccine cold chain, see the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) publications in the list of references.

² Note that manufacturers may place future vaccines and their adjuvants together in packages containing a minimum of 50 10-dose vials. The manufacturers' liability stops when a package is opened and/or when adjuvants are separated from the vaccine. Prior to the outbreak of a pandemic, the Chief of Logistics (CoL) should discuss packaging requirements directly with WHO, UNICEF, and the manufacturers.

Before an event:

- Plan the minimum number of repackaging operations by sizing shipments according to the needs of the population at each destination; ship vaccine through as few distribution points as possible before it gets to its destination.
- Plan a supply of different-sized cold boxes in sufficient numbers to ship vaccine in different quantities.
- Regularly inspect physical integrity of shipment containers and replace them as needed.
- Ensure that trained and sufficient staff will be available at all times.
- Exercise packaging of vaccine and ancillary items.

During an event

- Clearly display details, such as the number of vials per package and the expiry date, on the outside of shipping containers and cold boxes.
- Repackage vaccine, needles, syringes, and other ancillary items together so that health providers can efficiently administer the vaccine, adhere to packaging protocols that the health authorities established in consultation with vaccine experts, logistics officials and manufacturers, and keep repackaging operations to a minimum to prevent mistakes and loss of vaccine and time.
- Ensure that each shipment is recorded and tracked by the country's IMS and that it produces shipping invoices.
- Estimate the size of shipping containers or cold boxes and the amount of ice or frozen ice packs to ensure the correct temperature during shipment; ship an additional cold box with more coolant packs for shipments that will take longer to arrive so that coolant packs can be replaced en route.
- Adhere to cold-chain management protocols, use anti-tampering procedures and mechanisms (tapes and locks), provide temperature-monitoring devices in each shipment or cold box, and inspect physical integrity of cold boxes or vaccine carriers and replace them as needed.

7.3.2.5 Making or buying coolant for repackaging operations

Operation: Make sufficient coolant packs for vaccine shipments at all levels.

Before an event

- Calculate the amount of coolant packs needed at specific times and specific places.
- Assess capacities of available government and private facilities and equipment to provide coolant packs, and use private enterprises if national capabilities are not sufficient.

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- Plan to ship sufficient amount of coolant with insulation when dispatching vaccine to rural areas with no electricity.¹

During an event

- Constantly monitor production and inventory of coolant packs to identify and resolve problems before they affect deployment.

7.3.2.6 Transporting vaccines and ancillary items

Operation: Transport vaccine and ancillary items to designated points using ground, air, and/or water. Ensure adequate fuel supplies and vehicle/equipment repair facilities are available.

Before an event

- Establish a schedule of deliveries at all levels, showing times, type of transport, and names of individuals that will be required to service, fuel, and drive the vehicles; estimate the cost of maintaining the transport fleet, including per diem.
- Determine the mode of transport to each distribution point and facilities for refueling and repairs.
- Identify high-risk routes due to geographic conditions and/or security issues and establish procedures to protect staff, equipment, and shipments.
- Exercise activities involved in transportation and re-fuelling operations.

During an event

- Monitor availability of all transport resources and operators, dispatch schedules, and progress of the shipments to detect problems such as security, weather, and road conditions that may affect deliveries.
- Ensure a sufficient inventory of insulated containers for shipping vaccine if refrigerated vehicles are not available.
- Ensure that warehouses promptly report on the arrival and condition of shipments.

7.3.2.7 Managing supply chain information

Operation: Provide managers and staff with information needed to perform and coordinate supply chain activities. If deployment and vaccination data are to be publicized, ensure that the channels

¹ During the 1989–1991 polio eradication activities conducted by the Ministry of Health of Peru and the World Health Organization in the jungles of the Condorcanqui, the logistic teams successfully prolonged the efficacy of ice. They found that by packing large quantities of rice husks around big blocks of ice, they could preserve the ice for more than 5 days when it was stored inside a building on a cement floor at ambient temperatures greater than +25 °C. The thickness of the rice-husk packing was 25 to 40 centimetres and was replaced with a new layer of dry husks when it became saturated with water.

of communication (such as websites, social media, etc.) are working and that staff are aware of what type of information may be shared with the public.

Before an event

- Review Chapter 4 on establishing and maintaining a management information system to support supply chain operations. Ensure the system contains the following information:
- Transportation: transportation grid, location, and operational condition of available transport resources, including names of agencies and companies providing them; estimated travel time for each route; amount of fuel and oil required; and location of fuel and repair facilities.
- Stock inventory: balances, expiration dates, and lot numbers of vaccines at all levels; pending orders for vaccines by all levels; shipment details of all orders; status of warehouses; and receipts of inventory at all levels.
- Human resources: rosters showing number and type of human resources by function at each level, their availability, and their health status.

During an event

Use the MIS to:

- Contact warehouses and activate their staff, and identify sources of additional transportation and personnel.
- Monitor delivery of vaccines and identify routes where traffic, weather, security threats, or other factors that are causing delays that can be resolved by local law enforcement agencies; dispatch transport resources and operators and identify staff shortages at distribution points.
- Recall vaccine lots that cause severe reactions or are indicated to be ineffective.
- Report on status of operations to managers.

Update the MIS to record:

- Receipt and shipment of vaccine and ancillary supplies, their quantities at each location, status of shipments and transport, and condition of the vaccine and ancillary items on arrival.
- Status of deployment staff at each location and operational problems and security threats as they occur.
- Review government website as required and verify that the information displayed is correct.

7.3.3 Security¹

¹ See Chapter 5: Human Resources and Security.

7.4 Budgeting

The office or committee responsible for the country's response to a pandemic should work with the chief of vaccinations (CoV) and the chief of logistics (CoL) to calculate the cost of deployment operations and vaccination operations. Where the cost of a particular activity is unknown, a best estimate should be made, which should be periodically reviewed and updated. Once funds have been budgeted, they should be protected until the next pandemic, so that they can be quickly authorized for release when required.

7.4.1 Financial administration

Before a pandemic, the CoL should establish procedures for transferring funds to each warehouse, transportation facility, and health facility according to the budget, and organize exercises to test reporting and financial procedures. Accounting procedures must be in place, and requirements and format for reporting expenditures should be agreed upon. Staff should be informed of their responsibilities and trained to ensure conformity with reporting requirements established by the financial regulations.

During the deployment and vaccination campaign, a person responsible for managing financial operations should be assigned to ensure that regulations are respected and funds are distributed and transferred appropriately. Emergency procedures to transfer additional funds will need to be established to avoid any unforeseen disruption of deployment and vaccination activities due to a financial problem. Financial information on deployment operations at the end of the deployment and vaccination operations should be documented for future emergencies.

7.5 Conclusion

Effective management of supply chain logistic processes is essential for deploying vaccine within seven days. To ensure successful deployment, countries will need to define supply chain logistic processes at each level, identify surge capacity for storage and transportation, and conduct exercises to evaluate response preparedness of the country in the event of a pandemic. Once surge capacity requirements are defined, a budget should be established to support logistics and supply chain operations. Countries should also consider using a current supply chain delivery system. If no delivery system exists, consult WHO's website for information on developing a supply chain management system.¹

¹ For information on developing a supply chain management system, see http://www.who.int/immunization_delivery/optimize/en/

LOGISTICS AND SUPPLY CHAIN MANAGEMENT

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. Using and optimizing routine immunization systems and capacity proved critical to support pandemic logistics and vaccination operations. Current capacity should be assessed at all levels and compared to the requirements for deploying pandemic vaccine. When planning for future cold chain storage capacity for the routine immunization programme, expansion of storage spaces should be considered to allow for temporary storage of pandemic vaccines and other items.
2. Where expansion is not feasible, outsourcing additional storage capacity is an effective strategy to create additional surge capacity during a pandemic. Use of private or military services could be considered for transportation of vaccine.
3. Capacity building for human resources will be required in properly assessing the cold chain capacity essential at all levels, selection of cold chain equipment, proper distribution and management of vaccines and cold chain equipment, and their maintenance in emergency situations.
4. Exercises should be conducted regularly to identify remaining gaps in surge capacity and weaknesses in the supply chain logistic processes.

8. Managing waste

8.1 Overview

Waste management is a process of safely collecting and disposing of hazardous waste material (syringes, needles, vaccine vials in the case for vaccination). Properly managing waste during vaccination campaigns will eliminate potential hazards to medical personnel and the public and safeguard the environment. Done poorly, medical waste may cause blood-borne infections from sharps.

Vaccination for pandemic influenza will generate a vast amount of medical waste. Surge capacity must be planned to safely collect, transport, and dispose of these items. Although the routine national immunization programmes in many countries include a service for the collection and disposal of medical waste, experience shows that, even during standard immunization campaigns, such services are overloaded and additional services are required.

This chapter provides guidance for the chief of logistics (CoL) and other responsible officials to plan and manage the safe disposal of hazardous medical waste.

GOAL

Plan surge capacity to safely collect medical waste generated by vaccination activities during a pandemic, transport the waste to designated sites, and safely treat and dispose of it.

8.2 Objectives

Enable the CoL to:

- plan and manage the safe disposal of used injection equipment, vaccine vials, and other hazardous medical waste, and ensure that waste management systems are able to deal with the additional waste generated by a pandemic response; and
- record management details of dealing with the waste in the country's management information system (MIS).

8.3 Developing a waste management plan

The CoL should follow a three-step process to develop a sound waste management plan:

1. Assess existing capabilities.
2. Decide on methods of waste collection, transport, treatment, and disposal.
3. Establish a waste management strategy.

8.3.1 Assess existing capabilities

- List national regulations for the proper collection and disposal of medical waste, including injection waste.
- Identify all existing waste-disposal facilities and routes for collecting and transporting to disposal facilities, and document regions where appropriate facilities are not available.
- Determine the distance the CoL and other authorities plan to transport medical waste from remote areas for final disposal dependent on available resources. Plan to provide alternative methods for collection and disposal to avoid reuse of injection equipment and exposure of such hazardous material to the local community.
- Review information from the national immunization programme operations for the collection, treatment, and disposal of medical waste; in the case of services being provided by the private sector, seek relevant information regarding qualifications.
- Estimate the total daily amount of waste each immunization site will generate. Use that estimate to determine the capacity and cost of collecting and disposing of waste materials, the amount and types of transport required to collect it, and the time each vehicle will need to complete its assigned collection routes.
- Visit existing disposal sites (including private service providers) to ensure they comply with prevalent regulations, record the date of the facility's last inspection by responsible authorities, request a certificate of inspection (or similar document), and confirm that safe waste handling procedures are used.
- Review the quality and integrity of the equipment that incinerates the waste and ensure that it meets technical specifications for correct incineration temperatures.
- Contract private contractors to establish surge capacity to deal with pandemic waste; review and update the contracts as needed.

8.3.2 Decide on methods of waste collection, transport, treatment, and disposal

If their country lacks a written waste management plan, the CoL should decide on methods for collecting, transporting, treating, and disposing of waste based on national laws and codes. Planned activities and a budget should be in place. Periodically review all records, information, and practices in the waste management plan in view of experience gained from pandemic influenza A(H1N1) 2009 vaccination waste management operations.

At a minimum, recapping needles after injection should be discouraged and sufficient safety containers to collect used needles and syringes at all vaccination sites should be provided. Surge capacity to implement these methods should include a combination of locally available public and private capabilities, especially if the former cannot handle all waste. Decisions about proper handling of materials must be communicated to the managers who will be responsible for managing waste during the pandemic.

When these minimum waste guidelines are in place, the CoL and subordinate managers should then:

- determine the number of safety boxes or sharps containers that each vaccination site will require in accordance with the planned vaccination activities and ensure that the quantity are supplied and recorded in the inventory and management information systems; and
- coordinate with environmental, health, and other authorities to evaluate collection practices that have functioned well in the past and identify factors that have impeded proper practices.

This second step is aimed at revealing the various methods of disposal which are dependent on the estimated amount of waste, location (rural or urban) of the waste, and availability of local waste disposal facilities. Whatever method the CoL establishes, it must be safe, environmentally friendly, and in compliance with national health and safety codes and laws.

The WHO document, *Management of waste from injection activities at district level – A guide for district health managers*, provides tools for calculating the quantities of ancillary equipment needed to manage the disposal of used injection equipment.¹

8.3.3 Establish a waste management strategy

Based on the assessment of existing capabilities, the CoL should define a strategy to achieve the required surge capacity. State/municipal authorities, with technical assistance from environmental authorities and the national immunization programme, should review systems currently in place and determine how best to create this surge capacity. The CoL should then create a detailed waste management plan and obtain resources, including funding for operation.

Once an effective waste management strategy has been developed, the CoL should:

- assist health-care facilities to elaborate a “code of safe practices” for handling hazardous medical waste and designate a trained manager at each level to oversee and ensure compliance in public and private sector services;
- devise simple indicators to monitor the quality of waste management standards and practices;
- establish training programmes to ensure that staff at all levels comply with national and local laws, codes, and practices; and

¹ *Management of waste from injection activities at district level – A guide for district health managers*. Geneva, World Health Organization, 2006. (http://www.who.int/water_sanitation_health/medicalwaste/mwinjections/en/, accessed 25 June 2012.)

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- distribute pamphlets, notices, job descriptions, standard operation procedures, contact lists, and other relevant documents to all authorities, managers, and health-care workers that describe appropriate, compliant waste management standards and practices.

Once a waste management plan is established, the CoL should review, update, and test them frequently. Identify problems that would impede safe and rapid collection of waste followed by revision of the plan.

8.4 Performance indicators

Performance indicators should be established to assess compliance with waste disposal standards. Potential indicators are:

- the percent of health sites with sufficient safety containers for collection of needles and syringes;
- the percent of urban sites that collected their waste within one or more weeks after termination of the vaccination campaign and the percent of sites that reported their waste was not collected; and
- the percent of vehicles that completed their collection routes and delivered the waste to appropriate treatment and disposal sites.

The checklist in the supplementary documents include recommended standards and/or criteria for assessing whether the country's current deployment plan includes relevant processes and structures required to properly manage safe disposal of waste. If a country has no deployment plan, the checklist may be a template for developing one.

8.5 Budgeting

Actions required for maintaining and/or improving waste management practice and improving the capacity of countries to collect medical waste need to be carried out in advance of the next influenza pandemic. Using exercises and evaluations, in combination with the experience from pandemic vaccination exercises in 2009, on waste management operations, managers at each level should be in the position to prepare an operational budget. Once a pandemic has been declared, the waste management budget plan should include funds for covering logistic operations, contracts with private companies, per diem for staff, and repair and maintenance of vehicles and waste facilities.

8.6 Conclusion

Immunization for an influenza pandemic will generate a vast amount of medical waste. Countries must plan for surge capacity for safe collection, transport, and disposal of waste. Existing medical waste management systems in support of routine immunization programmes should be prepared to handle a large volume of additional waste. Collection and disposal methods should be based on national laws and codes, and management details of waste should be recorded in the MIS. Use of a private sector contractor could be considered, especially in countries where this service is mainly

provided by the private sector. Well-managed waste disposal eliminates a health hazard to medical personnel and the public and also safeguards the environment.

MANAGING WASTES

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. Countries and regions should document and share the lessons learned from their 2009 vaccination campaigns. This experience and the best practices acquired can help other countries plan for waste management and identify required surge capacity to collect, transport, and dispose of medical waste. Such planning has to start now so countries have the required capacity to handle waste appropriately and safely when a pandemic occurs.

9. Post-deployment surveillance and management of adverse events following immunization

9.1 Overview

The practice of monitoring a pharmaceutical or biological product including pandemic vaccine after it has been released for use is known as Post-deployment Surveillance (PDS). The main objective of PDS is to monitor the performance safety and effectiveness of the product. The purpose of safety monitoring in this phase of vaccine use is to detect vaccine-related reactions in order to complete the knowledge on the safety profile of the vaccine, as well as to detect programmatic errors. Effectiveness and safety data of pandemic vaccines can only be obtained after its widespread use. Planning for real-time evaluation is therefore critical and requires assessment of capacities and resources available to collect, manage, and measure a large data set generated over a short period of time.

Today, many countries have PDS systems that capture adverse events following immunization (AEFIs) and for investigation of serious adverse events (SAEs). A PDS system can be based on (a) active surveillance, with specific activities and trained staff for actively monitoring groups of persons, usually with a focus on selected AEFIs or adverse events of special interest (AESI) central to its operations, or (b) passive surveillance where AEFI cases are reported to the system. Such passive surveillance systems may also record reported data for selected reportable AEFIs only (e.g. SAEs) as the focus of its operations.

When using a novel pandemic influenza vaccine, both active and passive surveillance systems should allow flexibility and be able to capture and analyze large amounts of specific data in a short period of time from different populations and age groups. This was not the case for many countries during the 2009 pandemic. The ability to have flexible and robust PDS/AEFI system must be planned for, budgeted, and tested before the next influenza pandemic.

GOAL

Establish or enhance surge capacity of PDS for monitoring safety and effectiveness when using a novel pandemic influenza vaccine.

9.2 Objectives

Enable the chief of vaccination (CoV) to:

- include enhanced PDS in their national deployment and vaccination plans (NDVPs);
- evaluate their current PDS operations, and ensure they perform as required during an influenza pandemic; and
- establish managerial functions for planning, investigating, responding to, and monitoring AEFIs/AESIs.

9.3 Core components of active and passive monitoring

To allow countries to build databases that provide estimates of expected AEFIs and draw conclusions regarding causes of vaccine reactions, both active and passive monitoring approaches require the following core components:

- a system for detection and reporting adverse events following immunization (AEFIs);
- capacity to rapidly investigate, analyze data from, and manage reported AEFIs;¹
- a process for taking corrective actions given the type of the problem detected;
- a process for communicating information on reported AEFIs, safety profile of the vaccine(s) being used, and, if possible, information on the vaccine effectiveness; and
- capacity to evaluate operational limitations of their PDS system.

9.4 Importance of PDS post-deployment surveillance systems for national deployment and vaccination plans

It is essential that national and subnational authorities, deployment and vaccination managers, health-care workers, and the general population are sensitized to the importance of reporting AEFIs in order to obtain maximum information from the use of a novel influenza vaccine. The public demand for vaccines may change considerably during the course of a pandemic, and this also has a direct impact on post-deployment surveillance (PDS).²

The PDS system for pandemic vaccines should:

- use a predetermined set of case definitions for capturing adverse events of special interest (AESIs); reviewing data collected from the pandemic influenza A(H1N1) 2009 event will be a valuable tool;
- capture safety and effectiveness-related data in a format that is easy to analyze and share with counterparts at all levels, including with other countries and agencies;

¹ *Aide Memoire. Adverse Events Following Immunization (AEFI): Causality Assessment.* Vaccine Assessment and Monitoring. Department of Immunization, Vaccine & Biologicals. Geneva, World Health Organization, undated. (http://whqlibdoc.who.int/aide-memoire/a87773_eng.pdf, accessed 25 June 2012.)

² Expert Committee on Biological Standardization: Proposed Guidelines for Regulatory Preparedness for Human Pandemic Influenza Vaccines. Geneva, World Health Organization, 2007. (http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/Human_pandemic_Influenza_Vaccines_BS2074_01Feb08.pdf, accessed 25 June 2012.)

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- contribute to the risk-benefit evaluation of their use in real time; and
 - enable authorities to quickly and adequately assess vaccine safety, immunogenicity, and effectiveness, thereby allowing for informed changes in the vaccination programme.

Countries that do not use seasonal influenza vaccine lack baseline data on safety, immunogenicity, and effectiveness for assessing expected rates of AEFIs. As a result, it is a challenge for such countries to manage AEFI/AESI data from use of a novel pandemic influenza vaccine. In addition, the PDS system has to be able to address a range of different situations including:

- use of more than one vaccine formulation in a single country, different formulations for the first and second doses, use of new substrates in vaccine production, and different routes of vaccine administration;
- programmatic errors such as not following vaccine manufacturer specific instructions regarding the mixing of the specific adjuvant with the antigen, or failure to adhere to time limits on the use of the vaccine once mixed; and
- vaccination of priority groups with the novel vaccine.

Each country will need to assess surge capacity requirements to ensure that their PDS system can rapidly and effectively process large amounts of data. Processes that should be reviewed include:

- establish baseline studies to determine background incidence of AEFIs/AESIs and rates of risk factors from the use of seasonal influenza vaccine, or use of data from other countries;
- determine additional resources to enhance the current structure for collecting and reporting data so that a robust and efficient mechanism is easily established for reporting of adverse events locally, nationally and to global networks;
- Develop unified registries of vaccinated people to permit collection of data for analysis;
- Increase number of staff, assigning roles and providing training to staff in the public and private sector to carry out PDS functions required; and
- Increase laboratory capability to process all samples submitted for analysis according to Good Laboratory Practices (GLP); including establishing contracts with private laboratories for handling surge capacity especially for diagnosis of severe cases of interest.

9.5 Planning for post-deployment surveillance systems to support operations

Countries should have a process and designated staff to establish data collection protocols, review cases, as well as procedures to assess causality of serious AEFIs. It is also recommended that they have an expert committee (or access to the appropriate experts) perform a causality assessment, which should include risk-benefit considerations contingent to continuing the vaccination programme. The assessment should also account for performance of the pandemic vaccine in high-risk groups and recommend necessary changes.

During a pandemic, both active and passive surveillance systems are recommended because together they permit timely data acquisition and analysis of SAEs, such as Guillain-Barré syndrome (GBS).¹ A PDS system for safety should include:

- staff training in the detection, management, and reporting of AEFIs identified through passive and active surveillance;
- proper supervision to ensure that sites are reporting serious and non-serious AEFIs and that proper case investigation is carried out;
- working case definitions, procedures for correction of the problem if an AEFI was caused by programme error, and a protocol to follow in case of the suspension of vaccine use;
- laboratory capacity to process specimens and access to the clinical capacity to correctly diagnose and treat medical events presenting as AEFIs and to follow up on patients;
- communication protocol to inform the public on results of any investigation or rumours, including use of a trusted spokesperson and a website for the public to access information; and
- an operational budget for use during a pandemic, especially travel and per-diem funds for an investigation team.

In order to maintain confidence in vaccination services, it is essential that national level managers anticipate the most common crises, including incidences of AEFIs that may occur, and be prepared to deal with them. This involves encouraging communication between health-care workers and the community in order to obtain timely information, then verifying the facts before making any public statement and being familiar with the plan for reacting to such a crisis.

9.6 Performance indicators

Countries can use the following performance indicators to assess national capability and capacity to monitor safety issues of both seasonal and pandemic influenza vaccines:

- availability of guidelines and procedures for monitoring and management of AEFI are published and distributed at all levels, including to health-care workers;
- roles and responsibilities of key stakeholders are defined, documented, and disseminated;
- routine training and information on influenza-related AEFI monitoring and management for staff responsible in the PDS systems, including training and updating of laboratory staff;
- established system for regular review and sharing of safety and effectiveness data;
- a functional communication system for safety-related issues has been tested and the capacity to detect and investigate significant vaccine safety issues is exercised;
- protocols to guide action to measure vaccine performance are published and disseminated; and
- post-deployment safety monitoring is included in the deployment authorization process.

¹ Guillain-Barré syndrome (GBS) is an uncommon peripheral nerve disorder that, in rare cases, can follow vaccination. GBS is being followed up by several surveillance systems around the world due to the concern about an increased risk that might occur after vaccination against pandemic influenza A(H1N1) 2009.

9.7 Budgeting

Using exercises and evaluation in combination with the information from 2009 post-deployment operations, managers at each level should be able to prepare an operational budget in advance of the next pandemic. This could include upgrading the PDS system and laboratory facilities to assure that these processes and structures are supported. The plan should include funds for covering operations related to PDS activities, contracts with private laboratories, per diem for staff, and purchase of laboratory materials as well as training on PDS and management of AEFIs.

9.8 Conclusion

Real-time evaluation of the safety and efficacy of pandemic influenza vaccine requires accurate and prompt data to inform rapid decision making. Countries should strengthen their systems for post-deployment surveillance and management of AEFIs to ensure that they are capable of capturing and analyzing large amounts of specific data in a short period of time from different populations and age groups. This requires advance planning, budgeting, exercising, and training in surveillance and investigation as well as enhancing laboratory capacity.

POST-DEPLOYMENT SURVEILLANCE AND MANAGEMENT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. Countries should evaluate their systems and incorporate experience gained from using the pandemic influenza A(H1N1) 2009 vaccine. This evaluation may uncover limitations in their system and determine whether the system is robust and flexible enough for a future influenza pandemic. Actions required to ensure that post-deployment surveillance (PDS) systems are resilient should be carried out in advance.
2. Continuous and transparent communication with the public and media on the surveillance and investigation of adverse events following immunization (AEFIs) are required to maintain public trust, especially when the disease caused by a circulating pandemic influenza virus is moderate or is perceived to be less serious than the illness caused by the normal seasonal influenza virus.
3. Use and regular evaluation of the current AEFI surveillance systems in place for national immunization programme provides the platform for enhancing or creating surge capacity when using a pandemic influenza vaccine.
4. Human resources capacity in AEFI surveillance, including investigation and management of AEFI cases, should be strengthened, especially for district health facilities.
5. Adequate funds for PDS surge capacity should be budgeted within the national deployment and vaccination plan (NDVP) and should cover regular system updates, training of health staff in surveillance and investigation, and enhanced laboratory capacity.

10. Termination of deployment and vaccination operations

10.1 Overview

Termination of activities by the Chief of Logistics (CoL) and Chief of Vaccination (CoV) when the vaccination campaign finally concludes is an official part of the deployment and must be planned. This phase includes releasing staff to return to their original duty stations, returning resources and equipment to the authorities and agencies that provided them, and documenting lessons learned. The CoL and CoV will report what went well and what should be done differently to speed up future deployment and vaccination operations, and submit this information to the Incident Commander (IC) for consolidation with that of other responders to the pandemic.

GOAL

Ensure that deployment and vaccination operations are terminated in a planned manner, resources and capital assets are returned to the agencies that provided them, and lessons learned are properly documented for future emergency responses.

10.2 Objectives

Enable countries to:

- plan termination activities;
- document resources used and return unused resources to agencies that provided them; and
- document lessons learned during the deployment to define what worked well and what should be improved.

10.3 Activities

The public health authority should officially inform the public and national and international institutions involved in the response of the end of the pandemic in their country. Following this, the IC should issue an official statement to announce that response operations are terminating.

10.3.1 Cessation of vaccination activities

Once the end of response activities has been declared, the CoV and CoL should:

- recall excess stocks of vaccine and ancillary products and record their return in the management information system (MIS);
- certify that all remaining stocks of vaccine, supplies, and equipment have been returned and stored appropriately, and close administrative files related to the deployment;
- determine what to do with unused or expired vaccine; and
- confirm that those responsible for the disposal of medical waste have completed their operations.

To perform these tasks effectively, managers will need reports on the number of doses of vaccine and the quantities of other supplies sent to each designated point. Health-care staff at the distribution points can assist in this effort by determining the amount of vaccine and other supplies that remain compared to the number of people vaccinated. This information is critical, particularly if a second dose of pandemic influenza vaccine is required.

10.3.2 Documenting resources used

If the relevant data is entered before and during deployment and vaccination operations, the MIS will provide much of the data required for documenting the use of resources, such as numbers of vaccination sites, doses shipped and administered, costs for personnel, communications and private contracts, and number of transport resources.

Daily logs kept by supervisors should provide other information such as factors that affected staff performance, problems they encountered, and solutions to the problems. This information will be important in preparing a final report for agencies/ministries that supported the deployment. It will also be helpful when giving recognition to staff members for their dedicated service.

10.3.3 Documenting waste management operations

The volume of waste generated by vaccination activities will be enormous. Countries need to pay special attention to planning their waste management operations and termination activities. If waste management plans and capacity are inadequate, several weeks may lapse before all waste is properly collected, transported and processed for disposal. As a consequence, a report of lessons learned from the waste management activities may only be available after the report on other deployment and vaccination activities is produced.

10.4 Lessons learned

Documenting the lessons learned from deployment and vaccination operations will provide essential information about the effort and improve planning for other emergency responses. Lessons learned will only be beneficial, however, if supervisors and others record and rigorously describe both positive and negative operations, performance, and observations.

In addition to reviewing the logs and various forms completed by supervisors, the following activities may be of assistance in documenting the lessons learned:

- conducting workshops and surveys;
- interviewing staff and others involved in deployment and vaccination operations;
- reviewing reports, communications records, and staff performance; and
- retrieving data from the MIS.

The termination report on deployment and vaccination will document how and whether the vaccine was deployed within seven days and administered rapidly. The IC, CoL, and CoV will have to agree on the contents and scope of the report. If a country exercises its deployment or vaccination plan regularly before an event and continuously trains and updates its staff on all aspects of the plan, its report should reflect a job well done.

10.5 Conclusion

Termination of operations is an official part of the deployment and vaccination process and should not be overlooked. Like all other aspects of the NDVP, it needs to be planned in advance to ensure that operations are terminated in an orderly manner, resources and capital assets are returned to the agencies that provided them, and lessons learned are documented for future responses.

TERMINATION OF DEPLOYMENT AND VACCINATION OPERATIONS

Key recommendations from the pandemic influenza A(H1N1) 2009 deployment and vaccination experience

1. A termination report should be written, documenting to what extent vaccine was deployed within seven days and whether it was administered rapidly. Types of information to be included should be determined in advance.
2. Lessons learned from deployment and vaccination should be collated. They will provide essential information for more efficient operations during the next influenza pandemic.

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Annex 1

Sample template for drafting a national deployment and vaccination plan for pandemic influenza vaccine

Table of Contents

Executive Summary

Introduction

- Legal Basis or Resolutions
- Purpose: Save lives/mitigate the effects of an influenza pandemic
 - Text and/or table showing priority groups targeted for vaccination and estimated population for each group in rank order
 - Goal: Distribution of vaccines and ancillary items in seven days
 - Doses to be distributed
 - Number of syringes/safety boxes to be distributed
 - Summary text on costs or table with details to annex
- Expected results: Total number of persons to be vaccinated.

I. Vaccination strategies

- Brief text on how each target group will be vaccinated
- Table listing number of people that would be targeted by geopolitical areas with a detailed annex by state/district and catchment health facilities. A separate table for vaccinating each target group should be prepared unless a country can combine vaccination of two groups together
- Number of teams that will be required to vaccinate different target groups
- A table listing resources required at each level for vaccinating different target populations, and any additional types of support that the government will request from external sources
- Costs (Plan of Action [PoA])

II. Management and organization

- Brief description of the organization of the office that will manage and direct deployment operations of the pandemic influenza vaccine.
 - Annexes: Names and contact details (confidentiality issues)
 - Responsibilities and relations with other ministries, other government institutions, including those at state and local levels

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- Ministries, agencies, civic groups, and other NGOs that are part of the deployment committee or work with the office responsible for deployment operations and their objectives or roles and responsibilities. Annexes: Lists of names and their titles
 - Description of the operational relationships with governmental and civil society organizations at national and sub-national levels (district)
 - Administrative costs (PoA) such as communications, transport, etc.
 - Administration (Optional)
 - Location of office
 - Description of different staff positions
 - Summary of financial rules and reporting requirements including standardization of expenditure and financial reports

III. Legal and regulatory planning

- Brief description of legal and regulatory requirements, importation procedures and customs clearance, and challenges regarding importation and use of new pandemic influenza vaccine in the country

IV. Communication and information

- Brief description of the issues, requirements, and challenges regarding the flow of information and ability to communicate across government agencies and down the system to support deployment operations and vaccination plans
- Distribution Plan
 - Brief text on objective, issues and challenges, and estimated time to complete the distribution and vaccination for target groups
 - Process (software/other needs) and communication (hardware needs)
 - Costs (PoA)

V. Human resources and security

- Description of current human resources capacity available for executing a seven-day deployment and gap analysis;¹ Conclusion; Statement on whether additional human resources are needed.
- Estimated costs to finance/close the gap for human resources²
 - Brief text highlighting major requirements by category and why
 - Summary table(s) of a national overview of human resources by category
- Training of human resources
 - Description of training requirements³

¹ If the Deployment Plan will include operational issues regarding vaccination tactics to rapidly immunize a community, the appropriate section with text should be added, including the relevant tables.

² *Management of waste from injection activities at district level – A guide for district health managers*. Geneva, World Health Organization, 2006. (http://www.who.int/water_sanitation_health/medicalwaste/mwinjections/en, accessed 25 June 2012.)

³ *Management of waste from injection activities at district level – A guide for district health managers*. Geneva, World Health Organization, 2006. (http://www.who.int/water_sanitation_health/medicalwaste/mwinjections/en, accessed 25 June 2012.)

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- Supervisory training (programmatic benefits obtained)
 - Training plan, methods, and timeline as part of PoA
 - Costs for national PoA and summary cost table for each level
 - Security
 - Description of problems and brief text highlighting major requirements and security concerns as well as a security plan
 - Costs (PoA): Summary table for each level and maps/table showing areas where security issues are of concern
 - Annex (optional): List of security firms and their details

VI. Public communication

- Description of key issues surrounding communication activities regarding the use of pandemic influenza vaccine
- Messages to educate the community on why only certain groups are targeted
- Summary tables of needs with costs (PoA)

VII. Supply chain management

- Description of the distribution processes to achieve a seven-day deployment and a summary of the gaps and challenges
- Summary of the volumes, doses, and ancillary items to be distributed by areas/zones
- Cold chain: Brief description of the issues, requirements, and challenges; summary tables of requirements to support deployment and vaccination of target groups
- Transportation: Brief description of the issues, requirements, and challenges
- Costs (PoA): Summary table with an overview by state/province/district
- Annexes (optional)

VIII. Managing waste

- Brief overview of the waste to be generated from a vaccination campaign and what is needed to process it.
- Summary of the volume of waste to be generated by type: table – national overview, and challenges by areas/zones.
- Summary of transportation requirements to collect waste, time and quantity of transport to be used; number of contracts to be issued
- Costs (PoA): summary table: national overview and by state/district

IX. Post-deployment surveillance and management of AEFI

- Description of key issues surrounding PDS and AEFI for use of a pandemic vaccine, requirements and challenges of AEFI,
- line of reporting and roles and responsibilities of staff
- Costs (PoA): summary table

X. Termination of the deployment and vaccination operations

- Outline Deployment Termination Report
- Description of the evaluation plan including methods to be used, components of plan to be evaluated and how it will be executed
- Summary of deployment and vaccination costs: brief text and a table providing a national overview. Details according to country requirements

XI. Summary of budget requirements

- Components
- Estimated budget requirements by component and total requirements
- Funding available by component and total available funds (national and external)
- Funding requested from other sources by component and total funding requested

Annex 1: Plan of actions

- Description of activities by component
- Timeline
- Budget requirements for each activity
- Funding sources (national and external)
- Funding gaps
- An example of a plan of action can be found in the supplementary documents.

Other Annexes as determined by the country

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